# IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON and WISCONSIN; the DISTRICT OF COLUMBIA, THE CITY OF CHICAGO and THE CITY OF NEW YORK; *ex rel.*, CHARLES ARNSTEIN and HOSSAM SENOUSY,

No. 13 Civ. 3702 (CM)

Plaintiffs and Relators,

VS.

TEVA PHARMACEUTICALS USA, INC.; TEVA NEUROSCIENCE, INC.; and TEVA SALES AND MARKETING, INC.,

Defendants.

**JURY TRIAL DEMANDED** 

#### THIRD AMENDED FALSE CLAIMS ACT COMPLAINT

On behalf of the United States of America ("United States"), the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington and Wisconsin (collectively, the "States"), the District of Columbia ("D.C."), the City of Chicago and the City of New York (collectively, the "Cities" and, together with the United States, States and D.C., the "Government"), and pursuant to the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. §§ 3729-3733 and the False Claims Acts of the States, D.C. and the Cities,

Plaintiffs-Relators, Charles Arnstein ("Plaintiff-Relator Arnstein") and Hossam Senousy ("Plaintiff-Relator Senousy") (collectively, "Plaintiffs-Relators"), file this *qui tam* Third Amended Complaint ("Complaint") against Defendants, Teva Pharmaceuticals USA, Inc. ("Teva USA"), Teva Neuroscience, Inc. ("Teva Neuroscience") and Teva Sales and Marketing, Inc. ("Teva Sales and Marketing") (hereinafter collectively referred to as "TEVA," "Defendant," "Defendants" or the "Company"), and allege as follows:

#### I. INTRODUCTION

- 1. This case involves TEVA's illegal scheme, and related unlawful marketing, promotional and sales practices, to induce physicians to write prescriptions for Copaxone®¹ and Azilect® (the "Covered Drug(s)") by paying them as "speakers" or "consultants" in connection with sham speaker programs and events. As a direct result of the illegal payments from TEVA, these paid physicians have prescribed the Covered Drugs and influenced other physicians to do the same.
- 2. TEVA's illicit scheme was and is widespread and orchestrated from the highest levels of the Company.
- 3. TEVA's practices violate, *inter alia*, the federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"), and each of the States', D.C.'s, and Cities' counterparts, as well as the federal healthcare Anti-Kickback Statute ("AKS" or "AKA"), 42 U.S.C. § 1320a-7b(b), because they resulted in requests for payment by Medicare, Medicaid, TRICARE, and other federally-funded or state/local-funded government healthcare programs (hereinafter referred to as "Government Healthcare Program(s)") for the Covered Drugs.

<sup>&</sup>lt;sup>1</sup> Copaxone was marketed and sold in a 20 mg dosage from 1996 until 2014. In 2014, TEVA also released a 40 mg dosage of Copaxone, which requires less frequent injections by the patient.

#### II. FEDERAL JURISDICTION AND VENUE

- 4. Teva USA, Teva Neuroscience, and Teva Sales and Marketing are subsidiaries of Teva Pharmaceutical Industries, Ltd., a world-wide pharmaceutical company engaged in the development, manufacturing, marketing and sale of pharmaceutical products, including specialty medicines, generic and over-the-counter ("OTC") products, active pharmaceutical ingredients, and novel new therapeutic entities. Teva Pharmaceutical Industries, Ltd. is an Israeli corporation having its principal place of business at 5 Basel Street, P.O. Box. 3190, Petach Tikva 49131, Israel.
- 5. Defendant, Teva USA, is domiciled in the Commonwealth of Pennsylvania, with its principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454. Teva USA does business throughout the United States, including in the Southern District of New York.
- 6. Defendant, Teva Neuroscience, is a division or operating unit of Teva USA, and is domiciled in the State of Kansas with its principal place of business at 11100 Nall Avenue, Overland Park, Kansas 66211. Its principal place of business was formerly at 901 E. 104th Street, Suite 900, Kansas City, Missouri 64131. Teva Neuroscience does business throughout the United States, including in the Southern District of New York. Until the creation of Teva Sales and Marketing, Plaintiffs-Relators were considered to be employees of Teva Neuroscience and took direction from Teva Neuroscience.
- 7. Defendant, Teva Sales and Marketing, is a new legal entity created at the direction of Teva USA and also is a division of Teva USA. Effective January 1, 2014, all Teva Neuroscience employees were transferred to Teva Sales and Marketing. Upon information and belief, Teva Sales and Marketing is domiciled in the Commonwealth of Pennsylvania, with its

principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454. Teva Sales and Marketing does business throughout the United States, including in the Southern District of New York. Plaintiffs-Relators are currently considered to be employees of Teva Sales and Marketing and take direction from Teva Sales and Marketing. Plaintiffs-Relators, however, are compensated and have their expenses paid by Teva Neuroscience in its capacity as an operating unit of Teva USA.

- 8. Defendants, Teva USA, Teva Neuroscience, and Teva Sales and Marketing, are and function as alter egos of each other, as a joint entity, as an integrated enterprise and/or as agents of each other. At all pertinent times, Teva USA controlled, directed and supervised the sales and marketing activities of Teva Neuroscience and Teva Sales and Marketing, as well as their employees, including Plaintiffs-Relators, and each of the Defendants is legally responsible for the actionable conduct detailed in this Complaint. At all pertinent times, the employee and labor relations, as well as the compensation and benefit activities and the sales and marketing policies and procedures of TEVA have operated from and through the centralized control of Teva USA, which has established employee and labor relations, compensation and benefits and sales and marketing policies and procedures for Teva Neuroscience and Teva Sales and Marketing.
- 9. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732. This Court has supplemental jurisdiction over the counts relating to the state FCAs pursuant to 28 U.S.C. § 1367.
- 10. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. §3732(a) because Defendant can be found in, resides, or transacts business in this District.

Additionally, this Court has personal jurisdiction over Defendant because acts prohibited by 31 U.S.C. § 3729 occurred in this District.

- 11. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendant transacts business in this District and numerous acts proscribed by 31 U.S.C. § 3729 occurred in this District.
- 12. Plaintiff-Relator Arnstein was formerly employed by TEVA as a sales representative. He was hired by TEVA in January 2006 and presently resides in Henry County, Indiana.
- 13. Plaintiff-Relator Senousy also was formerly employed by TEVA as a sales representative. He was hired by TEVA in February 2002 and presently resides in Hendricks County, Indiana.
- 14. Plaintiffs-Relators have complied with all procedural requirements of the laws under which this case is brought.
- 15. Plaintiffs-Relators' claims and this Complaint are not based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party, as enumerated in 31 U.S.C. § 3730(e)(3).
- 16. Plaintiffs-Relators are the original sources of the information upon which this Complaint is based and the facts alleged herein, as that phrase is used in the FCA and other laws at issue in this Complaint.
- 17. Plaintiffs-Relators bring this action based on their direct knowledge and, where indicated, on information and belief. None of the actionable allegations set forth in this Complaint are based on a public disclosure as set forth in 31 U.S.C. §3730(e)(4).

- 18. At all times relevant hereto, TEVA acted through its agents and employees, and the acts of TEVA's agents and employees were within the scope of their agency and employment. The policies and practices alleged in this Complaint were, on information and belief, established and/or ratified at the highest corporate levels of Defendant. Among them are legacy executives from Cephalon, a U.S. biopharmaceutical company which TEVA acquired in 2011 and which, at the time of its acquisition, was subject to a five-year Corporate Integrity Agreement resulting in a \$425 million fine levied against Cephalon in 2007 as a result of its unlawful off-label marketing practices.
- Denying Defendants' Motions to Dismiss dated February 22, 2016 (the "Memorandum Decision and Order Decision"). Consistent with the terms of the Memorandum Decision and the amendments set forth in this Complaint, and for purposes of clarity, Plaintiffs-Relators do not allege or assert in the Complaint that (a) the submission of Prescription Drug Events ("PDEs") constituted false claims (either factually or legally) in violation of the FCA; (b) TEVA caused the submission of false claims in connection with the TRICARE program prior to March 23, 2010; or (c) Form CMS-1500 (08/05) forms the basis for any express certification claim, as compared to the current Form CMS-1500 (02/12), which, as detailed below, provides a basis for express certification claims.<sup>2</sup>

<sup>&</sup>lt;sup>2</sup>Plaintiffs-Relators recognize that the Court has stayed Defendants' Motions to Dismiss with respect to Counts II through XXXIII of the Second Amended Complaint (relating to various state and municipal laws). As Plaintiffs-Relators have determined that they are not able to assert cognizable claims under Maryland and New Hampshire law, they have eliminated claims under those states' laws from this Complaint in the interests of judicial economy at this time.

## III. THE REGULATORY ENVIRONMENT

- 20. Pursuant to the AKS, it is unlawful to knowingly offer or pay any remuneration, in cash or in kind, in exchange for the referral of any product (including a prescription drug product) for which payment is sought from any Government Healthcare Program, including Medicare, Medicaid, and TRICARE.
- 21. The AKS is designed to, *inter alia*, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry.
- ensure compliance with the provisions of the AKS and other federal laws governing the provision of healthcare services in the United States. Compliance with the AKS is expressly and impliedly required for reimbursement of Government Healthcare Programs federal program claims, and claims made in violation of the law are actionable civilly under the False Claims Act. See 42 U.S.C. § 1320a-7b(g) (2010) (a "claim that includes items or services resulting from a violation of . . . [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]. . . ."). Further, the United States has deemed violations of the AKS to be material to its decision to pay health care claims, demonstrated in part through the requirement that providers and suppliers certify compliance with the AKS as a condition of payment under Government Healthcare Programs. If the United States had been aware that the claims discussed herein resulted from conduct that violated the AKS, the United States would not have paid the claims submitted in connection with the Defendants' unlawful conduct.
- 23. The AKS prohibits suppliers such as pharmaceutical manufacturers from compensating, in cash or in kind, a healthcare provider when a purpose of the payment is to

influence the provider's prescribing habits or to gain favor for its product over the product of any competitor, and such conduct results in federal program expenditures.

- 24. A violation of the AKS is a violation of the federal FCA. The FCA, 31 U.S.C. § 3729, provides, in pertinent part, that:
  - (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government;

\* \* \*

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person.

### A. The FCA And The Medicare Fraud And Abuse/Anti-Kickback Statute

- 25. The FCA provides that any person who knowingly presents or causes another to present a false or fraudulent claim for payment or approval is liable for a civil penalty of up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. § 3729(a)(1)(A)&(B). The States, D.C., and the Cities that are parties to this Complaint have enacted FCA statutes that similarly apply to Medicaid fraud and/or fraudulent healthcare claims submitted for payment by municipal funds.
- 26. The federal healthcare AKS, 42 U.S.C. § 1320a-7b(b), which also applies to the state Medicaid programs and/or municipal programs, provides penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce the

referral of business reimbursable under Government Healthcare Programs. The offense is a felony punishable by fines of up to \$25,000 and imprisonment for up to five years.

- 27. The federal healthcare AKS arose out of Congressional concern that payoffs to those who can influence healthcare decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the Government Healthcare Programs from these difficult-to-detect harms, Congress enacted a prohibition against the payment of kickbacks in any form resulting in federal program expenditures, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.
- 28. The Balanced Budget Act of 1997 amended the federal healthcare AKS to include administrative civil penalties of \$50,000 for each violation, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a).
- 29. In accordance with the federal healthcare AKS, applicable regulations directly prohibit providers from receiving remuneration paid with the intent to induce referrals or business orders, including the prescription of pharmaceuticals paid as a result of the volume or value of any referrals or business generated, which results in federal program expenditures. *See* 42 C.F.R. § 1001.952(f). Thus, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others in order to recommend drugs that may be paid for by a Government Healthcare Program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company that has, as one of

its purposes, inducement of a physician to write additional prescriptions for the company's pharmaceutical products.

- 30. Such remunerations are kickbacks when paid to induce or reward physicians for writing prescriptions. Kickbacks increase Government-funded health benefit program expenses by inducing medically unnecessary overutilization of prescription drugs and excessive reimbursements. Kickbacks also reduce a patient's healthcare choices, as physicians may prescribe drug products based on the physician's own financial interests rather than according to the patient's medical needs.
- 31. The federal healthcare AKS contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. § 1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protects TEVA from liability for the conduct alleged herein.
- 32. The Patient Protection and Affordable Care Act ("PPACA"), Public Law No. 111-148, § 6402(g), amended the federal healthcare AKS, 42 U.S.C. § 1320a-7b(b), to specifically allow violations of its "anti-kickback" provisions to be enforced under the FCA. The PPACA also amended the Social Security Act's "intent requirement" to make clear that violations of its anti-kickback provisions, like violations of the FCA, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." Public Law No. 111-148, § 6402(h).
- 33. As detailed herein, TEVA devised a scheme whereby it paid kickbacks to physicians in the form of cash and cash equivalents with the specific aim of increasing the usage of the Covered Drugs.

34. Knowingly paying kickbacks to physicians to induce them to prescribe a prescription drug on-label or off-label (or to influence physician prescriptions) for individuals who seek reimbursement for the drug from a Government Healthcare Program or causing others to do so, while certifying compliance with the federal healthcare AKS (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA and similar state False Claims Acts.

# B. The Manner In Which The Government Healthcare <u>Programs Pay For The Covered Drugs</u>

- 35. For the Covered Drugs at issue, generally, when a physician prescribes a drug, a patient is provided with a prescription that is then filled at a pharmacy. The pharmacy then submits the claim for payment to the relevant Government Healthcare Program(s) for reimbursement. For Copaxone, TEVA generally first works with an MS patient to (a) establish coverage by a Government Healthcare Program or other insurance scheme, (b) ensure that the prescription is filled by a pharmacy (and delivered to the patient usually by mail), and (c) provide training and instruction on how Copaxone should be self-administered by injection by the patient. Once the patient is able to self-administer the drug by way of injection, Copaxone prescriptions are then filled by traditional and other pharmacies.
- 36. In certain circumstances, a Government Healthcare Program may also have pharmacy facilities that directly dispense prescription drugs. In such cases, the Government Healthcare Program purchases the drug directly rather than reimbursing the pharmacy.
- 37. <u>Medicare</u>. Medicare is a Government Healthcare Program that provides federally subsidized health insurance primarily for persons who are 65 or older or disabled. *See* 42 U.S.C. §§1395, *et seq.* ("Medicare Program" or "Medicare"). Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of

2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries. Medicare Part D became effective January 1, 2006. All persons enrolled in Medicare Part A and/or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. The Department of Health and Human Services ("HHS"), through its component agency, The Centers for Medicare & Medicaid Services ("CMS"), contracts with private companies (or "Part D sponsors") to administer prescription drug plans. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors enter into subcontracts with many pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

- 38. Generally, after a physician writes a prescription for a patient who is a Medicare beneficiary, that patient takes the prescription to a pharmacy to be filled. When the pharmacy dispenses drugs to the Medicare beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor (sometimes through the sponsor's pharmacy benefit manager, or "PBM"). The pharmacy receives reimbursement from the sponsor (or PBM) for the "gross drug cost" of the drug dispensed—the portion of the drug cost not paid by the beneficiary, the pharmacy's dispensing fee, and any applicable sales taxes.<sup>3</sup>
- 39. The Part D sponsor is then required to submit to CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event ("PDE"), which contains 39 data elements regarding the prescription claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount it has paid to the pharmacy, and whether the drug is covered under the Medicare Part D benefit.

<sup>&</sup>lt;sup>3</sup> The gross drug cost paid to a pharmacy for dispensing a covered drug is included in PDE data field 30 if the drug is dispensed to a beneficiary who is below the out-of-pocket threshold and data field 31 if the drug is dispensed to a beneficiary who is above the out-of-pocket threshold. *See CMS Updated Instructions: Requirements for Submitting Prescription Drug Event Data*, 4.27.2006, pg. 15.

- 40. Payments to a Part D Plan sponsor are conditioned on the provision of information to CMS that is necessary for CMS to administer the Part D program and make payments to the Part D Plan sponsor for qualified drug coverage. 42 C.F.R. §423.322. CMS's instructions for the submission of Part D prescription PDE claims data state that "information . . . necessary to carry out this subpart" includes the data elements of a PDE. *See CMS Updated Instructions: Requirements for Submitting Prescription Drug Event Data*, 4.27.2006, pg. 9. PDE records are an integral part of the process that enables CMS to administer the Part D benefit. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.
- D sponsor plan's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low-income subsidies. 42 C.F.R. §§423.315, 423.329. At the end of the payment year, CMS reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred. In this reconciliation process, CMS uses the PDE claims data it has received from the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D, such as the gross drug cost the sponsor paid to pharmacies for covered drugs.
- 42. If CMS underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference. If CMS overpaid the sponsor for low-income subsidies or reinsurance costs, it will recoup the overpayment from the sponsor. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed

by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. 42 C.F.R. §423.336.

- 43. The payments made by CMS to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. §423.315(a).
- 44. In order to receive Part D funds from CMS, Part D sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply with all applicable federal laws, regulations, and CMS instructions.
- 45. By statute, all contracts between a Part D Plan sponsor and HHS must include a provision whereby the Plan sponsor agrees to comply with the applicable requirements and standards of the Part D program, as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. §1395w-112.
- 46. Medicare Part D sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA and AKS. 42 C.F.R. §423.505(h)(1).
- 47. In accordance with these express statutory and regulatory requirements, all contracts entered into between CMS and Plan D sponsors from 2006 through the present include a provision in which the sponsor "agrees to comply with . . . federal laws and regulations designed to prevent . . . fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§3729, et seq.), and the anti-kickback statute §§1127B(b) of the Act."

- 48. CMS regulations further require that all subcontracts between Part D sponsors and downstream entities (such as pharmacies and PBMs) contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions, including the AKS. 42 C.F.R. §423.505(i)(4)(iv). Thus, subcontracting entities that certify compliance with all applicable laws and regulations are expressly certifying compliance with the AKS.
- 49. A Part D sponsor also is required by federal regulations to certify to the accuracy, completeness and truthfulness of the PDE claims data submitted to CMS. Specifically, the relevant regulatory provision, entitled "Certification of data that determine payment," provides in relevant part:
  - (I) General rule. As a condition, for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.
  - (2) Certification of enrollment and payment information. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.
  - (3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under §4523,328(b)(3) (or for fallback entitles, under §423.871(f) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. . . .

42 C.F.R. §423.505(k).

- 50. In making its certification to CMS, the sponsor relies upon the accuracy and integrity of the underlying claims information. 42 C.F.R. § 423.505(k)(3). CMS utilizes this information in the PDE at the end of the payment year to reconcile actual sponsor costs with advanced payments that have been made to the sponsor by CMS.
- 51. Compliance with the regulatory requirement that the PDE data submitted to CMS is "true, accurate, and complete" is a condition of payment under the Medicare Part D program to the extent that it involves a violation of the AKS.
- 52. In accordance with this regulatory requirement, since the Part D program began, Medicare required each Part D Plan sponsor to sign annually an Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor ("Attestation(s)"). This Attestation states: Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:

The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event (PDE) data that have been submitted to and accepted by CMS as of [date] with respect to the Part D plans offered under the above-stated contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the Part D Organization has been informed by May 30, [current year]. In addition, the Part D Organization attests based on best knowledge, information, and belief, the payments that have been made by the Part D Organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last successful DIR [Direct and Indirect Remuneration Date [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration date submitted to CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the

requirements in the Medicare Part D program regulations and the Final Medicare Part D DIR Reporting Requirements for [the prior year]. The Part D Organization also certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution.

- 53. All approved Part D sponsors who received payment under Medicare Part D in benefit years 2006 through the present date submitted these required Attestations in the same or similar format. *See, e.g.*, CMS 2008 Regional Prescription Drug Event Data Technical Assistance Resource Guide, Attachment 1 Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor, pg. 385.
- 54. Medicare regulations further provide: "If the claims data are generated by a related entity, contractor, or subcontractor of a Part D Plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. §423.505(k)(3).
- 55. These requirements are plainly summarized in CMS's Medicare Prescription

  Drug Benefit Manual, ch. 9 § 80.1:

When submitting claims data to CMS for payment, Sponsors and their subcontractors must certify that the claims data is true and accurate to the best of their knowledge and belief. The False Claims Act is enforced against any individual/entity that knowingly submits (or causes another individual/entity to submit) a false claim for payment to the Federal government.

56. Medicare also enters into agreements with physicians to establish the physician's eligibility to participate in the Medicare program. For the physicians to be eligible for participation in the Medicare program, physicians must certify that they agree to comply with the AKS, among other federal health care laws. Specifically, on the Medicare enrollment form, CMS Form 855I, the "Certification Statement" that the medical provider signs states: "You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below." Those requirements include:

I agree to abide by the Medicare laws, regulations and program instructions that apply to me . . . The Medicare laws, regulations and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

\*\*\*\*

I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

- Medicaid. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a state Medicaid program. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§1396, 1396a(a)(13), 1396a(a)(30)(A). While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.
- 58. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to

the national average. 42 U.S.C. §1396d(b). Among the states, the FMAP is at least 50 percent and is as high as 83 percent. The federal government pays to the state the statutorily established share of the "total amount expended . . . as medical assistance under the State plan." 42 U.S.C. §1396b(a)(1).

- 59. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimate expenditures to actual expenditures). 42 C.F.R. §430.30.
- 60. Claims arising from illegal kickbacks are not authorized to be paid under state regulatory regimes. For example, the New York regulatory regime provides that an "overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake." N.Y. Comp. Codes R. & Regs. Title 18 §518.1(c). "Unacceptable practice" is defined to include "[b]ribes and kickbacks," *Id.* §515.2(b)(5), and lists within this category both "soliciting and receiving," *Id.* §515.2(b)(5)(ii), and "offering or paying," *Id.* §515.2(b)(5)(iv), "either directly or indirectly any payment

(including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the program," *Id.* §515.2(b)(5)(ii), (iv). New York's anti-kickback statute forbids kickbacks in similar terms. *See* N.Y. Soc. Serv. Law §§366-d-f.

- 61. Providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.
- 62. Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations.
- 63. In New York, for example, physicians and pharmacies must periodically sign a "Certification Statement for Provider Billing Medicaid," in which the provider certifies that claims submitted "to the State's Medicaid fiscal agent, for services or supplies furnished," "will be subject to the following certification. . . . I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations."
- 64. As reflected in the chart below, the following states have provider certification requirements for their Medicaid programs that are the same or similar to that of the State of New York in all material respects:

Alabama	The Provider Enrollment application that a provider is required to sign before it can participate in the State of Alabama Program requires a provider to agree to the following:
	"As a condition for participation as a provider under the Alabama Medicaid Program (MEDICAID), the provider (Provider) agrees to comply with all terms and conditions of this Agreement
	"§1.1. This Agreement is deemed to include all State and Federal laws and regulations.
	§1.2.3. This Agreement is subject to all state and federal laws and regulations relating to fraud and abuse in health care and the Medicaid program."
	See Alabama Medicaid Provider Enrollment Application, §§1.1, 1.2.3.
Alaska	The Provider Enrollment Form that a provider is required to sign before it can participate in the State of Alaska Program requires a provider to agree to the following terms and conditions:
	"1. To abide by federal Medicaid regulations and regulations of the Alaska Department of Health and Social Services pertaining to the furnishing of services or items or claiming payments under Alaska's Medical Assistance programs To ensure that my practice/business remains in compliance with all federal and state, laws, regulations, policies, and rules"
	See Alaska Medical Assistance Program, Provider Enrollment Form, at 4.
Arizona	The Provider Participation Agreement that a provider is required to sign before it can participate in the State of Arizona Program requires a provider to agree to the following terms and conditions:
	"6. The Provider shall comply with all federal, State and local laws, rules, regulations, standards and executive orders governing performance of duties under this Agreement, without limitation to those designated within this Agreement
	"13. By signing this Agreement, the Provider certifies that it has not engaged in any violation of the Medicare Anti-Kickback statute (42 USC §§1320a-7b"
	See Arizona Health Care Cost Containment System Administration Provider Participation Agreement, §111(6), (13).

Arkansas	The contract that a provider is required to sign before it can participate in the State of Arkansas Program requires a provider to agree to the following terms and conditions:
	"Provider, in consideration of the covenants therein, agrees: [t]o conform to all Medicaid requirements covered in Federal or State laws, regulations or manuals."
	See Contract to Participate in the Arkansas Medical Assistance Program, § l(K).
California	The Provider Agreement that a provider is required to sign to participate in the State of California Program requires a provider to agree to the following:
	"2. Compliance With Laws and Regulations. Provider agrees to comply with all applicable provisions of Chapters 7 and 8 of the Welfare and Institutions Code (commencing with Sections 14000 and 14200), and any applicable rules or regulations promulgated by DHS pursuant to these Chapters Provider further agrees to comply with all federal laws and regulations governing and regulating Medicaid providers."
	"3. Forbidden Conduct. Provider agrees that it shall not engage in conduct inimical to the public health, morals, welfare and safety of any Medi-Cal beneficiary, or the fiscal integrity of the Medi-Cal program."
	"14. Provider Fraud and Abuse. Provider agrees that it shall not engage in or commit fraud and abuse. 'Fraud' includes any act that constitutes fraud under applicable federal or state law."
	"18. Prohibition of Rebate, Refund, or Discount. Provider agrees that it shall not offer, give, furnish, or deliver any rebate, refund, commission preference, patronage dividend, discount, or any other gratuitous consideration, in connection with the rendering of health care services to any Medi-Cal beneficiary. Provider further agrees that it shall not solicit, request, accept, or receive, any rebate, refund, commission preference, patronage dividend, discount, or any other gratuitous consideration in connection with the rending of health care services to any Medi-Cal beneficiary. Provider further agrees that it will not take any other action or receive any other benefit prohibited by state or federal law."
	"Provider agrees that compliance with the provisions of this agreement is a condition precedent to payment to provider."
	See California Medi-Cal Provider Agreement.

Colorado	The Medicaid Provider Participation Agreement that a provider is required to sign to participate in the State of Colorado Program requires a provider to agree to the following:
	"A. Provider will comply with all applicable provisions of the Social Security Act, as amended; federal or state laws, regulations, and guidelines; and Department rules."
	See Colorado Medicaid Provider Agreement, Definitions ¶ A.
Connecticut	The Connecticut Medical Assistance Program application that a provider is required to sign to participate in the State of Connecticut Program requires a provider to agree to the following terms and conditions:
	"I further certify that, if I am granted status as a provider for Connecticut Medical Assistance programs, I expressly agree to the following terms and conditions: to abide by all applicable federal and state statutes and regulations."
	See Connecticut Medical Assistance Program Enrollment/ Re-Enrollment Application.
	In addition, the Provider Enrollment Agreement that a provider is required to sign to participate in the State of Connecticut's Program requires a provider to agree to the following terms and conditions:
	"Provider wishes to participate in the Connecticut Medical Assistance Program and, therefore, represents and agrees as follows:"
	"2. To abide by and comply with all federal and state statutes, regulations, and policies pertaining to Provider's participation in the Connecticut Medical Assistance Program."
	"26. Provider acknowledges and understands that the prohibitions set forth in [Section 1909 of the Social Security Act] include but are not limited to false statements, misrepresentation, concealment, failure to disclose and conversion of benefits and any giving or seeking of kickbacks, rebates, or similar remuneration[.]"
	See Connecticut Department of Social Services Health Care Financing, Provider Enrollment Agreement.

Delaware	The Contract for Items or Services Delivered to Delaware's Medical Assistance Program Eligibles that a provider is required to sign in order to participate in the State of Delaware's Program requires a provider to agree to the following terms and conditions:
	"1. Applicable Laws and Regulations
	The Provider agrees, as a participant in the programs under the authority of the Delaware Medical Assistance Program (DMAP), to abide by the rules, regulations, policies and procedures of the DMAP, and to comply with all the terms, conditions, and requirements as set forth herein The Provider also understands that penalties may be imposed for failure to observe the terms of the Social Security Act."
	"3. Payment for Items or Services
	The Provider shall not solicit, charge, accept, or receive any money, gift or other consideration from a DMAP eligible or from any other person on behalf of the eligible for any service or item allowable under the DMAP"
	See Delaware's Contract for Items or Services Delivered to Delaware Medical Assistance Program Eligibles.
District of Columbia	The Provider Agreement that a provider is required to sign to participate in the District of Columbia Program requires a provider to agree to the following:
	"C. To satisfy all requirements of the Social Security Act, as amended, and be in full compliance with the standards prescribed by Federal and State standards [and that]
	If the Department determines that a provider has failed to comply with the applicable Federal or District law or rule, the Department may do all of the following: A. Withhold all or part of the providers' payments"

See District of Columbia Medicaid Provider Agreement, at 20, 23.

#### Florida

The Medicaid Provider Agreement that a provider is required to sign to participate in the State of Florida's Program requires a provider to agree to the following:

"The provider agrees to comply with local, state, and federal laws, as well as rules, regulations, and statements of policy applicable to the Medicaid program, including the Medicaid Provider Handbooks issued by [the Florida Agency for Health Care Administration]."

See Non-Institutional Medicaid Provider Agreement.

In addition, Florida's Medicaid Provider Enrollment Application, which a provider is required to sign to participate in the State of Florida's Program, requires a provider to agree that:

"Providers who choose to submit claims electronically . . . must understand and agree to the following terms and conditions: . . . [a]bide by all Federal and State statutes, rules, regulations, and manuals governing the Florida Medicaid program."

See Florida Medicaid Provider Enrollment Application.

#### Georgia

The Statement of Participation that a provider is required to sign to participate in the State of Georgia's Plan for Medical Assistance Program requires a provider to agree to the following terms and conditions:

"2A. Legal Compliance. Provider shall comply with all of the Department's requirements applicable to the category(ies) of service in which Provider participates under this Statement of Participation, including Part I, Part II and the applicable Part III manuals."

"4A. Claim Submission; Certification of Claims. Provider shall submit claims for Covered Services rendered to eligible Medicaid recipients in the form and format designated by the Department. For each claim submitted by or on behalf of a Provider, Provider shall certify each claim for truth, accuracy and completeness, and shall be responsible for research and correction of all billing discrepancies without cost to the Department. This provision shall survive termination or expiration of this Statement of Participation for any reason."

"4D. Reimbursement for Covered Services. Reimbursement for Covered Services performed shall be made in a form and format designated by the Department. Payment shall be made in conformity with the provisions of the Medicaid program, applicable federal and state laws, rules and regulations promulgated by the U.S. Department of Health and Human Services and the State of Georgia, and the Department's Policies and Procedures manuals in effect on the date the service was rendered. . . . Provider agrees that the Department shall not reimburse any claim, or portion thereof, for services rendered prior to the effective date of enrollment indicated by the Department or for which federal financial participation is not available."

"Provider acknowledges that payment of claims submitted by or on behalf of Provider will be from federal and state funds, and the Department may withhold, recoup or recover payments as a result of Provider's failure to abide by the Department's requirements. This provision shall survive termination or expiration of this Statement of Participation for any reason."

See Georgia Statement of Participation, Department of Community Health, Division of Medical Assistance, § Ill (D).

Hawaii	The Hawaii State Medicaid Program Provider Agreement that a provider is required to sign to participate in the State of Hawaii's Program requires a provider to agree to the following:  "1. I/We agree to abide by the applicable provisions of the Hawaii State Medicaid Program and applicable provisions set forth in the Code of Federal Regulations (C.F.R.) related to the Medical Assistance Program. Upon certification by the Hawaii State Medicaid Program, I/We also agree to abide by the policies and procedures contained in the Hawaii State Medicaid Manual."  "6 I/We am aware that it is violation of Federal law to accept or require additional payments over and beyond those established by the Hawaii State Department of Human Services for services rendered under the Hawaii State Medicaid Program."  See Hawaii State Medicaid Program Provider Agreement and Condition of
Idaho	Participation, ¶ 1.  The Provider Agreement that a provider is required to sign to participate in the State of Idaho Program requires the following:  "1. Compliance.  To provide services in accordance with all applicable provisions of statutes, rules and federal regulations governing the reimbursement of services and items under Medicaid in Idaho, including IDAPA 16.03.09 and 16.03.10, as amended; the current applicable Medicaid Provider Handbook; any Additional Terms attached hereto and hereby incorporated by reference; and any instructions contained in provider information releases or other program notices."
	See Idaho Department of Health and Human Services, Medicaid Provider Agreement.

#### Illinois

The Agreement for Participation in the Illinois Medical Assistance Program that a provider is required to sign to participate in the State of Illinois' Program requires a provider to agree to the following:

- "1. The Provider agrees, on a continuing basis, to comply with all current and future program policy and billing provisions as set forth in the applicable Department of Public Aid Medical Assistance Program rules and handbooks."
- "3. The Provider agrees, on a continuing basis, to comply with Federal standards specified in Title XIX and XXI of the Social Security Act and with all other applicable Federal and State laws and regulations."
- "6. The Provider agrees to be fully liable for the truth, accuracy and completeness of all claims submitted electronically or on hard copy to the Department for payment. Provider acknowledges that it understands the laws and handbook provisions regarding services and certifies that the services will be provided in compliance with such laws and handbook provisions. Provider further acknowledges that compliance with such laws and handbook provisions is a condition of payment for all claims submitted. Any submittal of false or fraudulent claim or claims or any concealment of a material fact may be prosecuted under applicable Federal and State laws."

*See* Agreement for Participation in the Illinois Medical Assistance Program, ¶¶ 1, 3, 6.

#### Indiana

The Indiana Health Coverage Programs ("IHCP") Provider Agreement that a provider is required to sign to participate in the State of Indiana's Program requires a provider to agree to the following:

"By execution of this Agreement, the undersigned entity ("Provider") requests enrollment as a provider in the Indiana Health Coverage Programs. As an enrolled provider in the Indiana Health Coverage Programs, the undersigned entity agrees to provide Medicaid-covered . . . services and/or supplies to Indiana Medicaid . . . members. As a condition of enrollment, this agreement cannot be altered and the Provider agrees to all of the following:..."

- "2. To comply with all federal and state statutes and regulations pertaining to the Medicaid Program or CHIP, as they may be amended from time to time."
- "5. To provide Medicaid-covered and CHIP-covered services and/or supplies for which federal financial participation is available for Medicaid and CHIP members pursuant to all applicable federal and state statutes and regulations."
- "11. To abide by the Indiana Health Coverage Programs Provider Manual [Chapter 13 of which defines Medicaid Fraud to include soliciting, offering, or receiving a kickback, bribe, or rebate]..."
- "13. To be individually responsible and accountable for the completion, accuracy, and validity of all claims filed under the provider number issued, including claims filed by the Provider, the Provider's employees, or the Provider's agents. Provider understands that the submission of false claims, statements, and documents or the concealment of material fact may be prosecuted under the applicable Federal and/or State law."
- "16. To submit claims that can be documented by Provider as being strictly for ... compensation that Provider is legally entitled to receive."

*See* Indiana Health Coverage Programs ("IHCP") Provider Agreement, ¶¶ 2, 5, 11, 16(c).

Iowa	The Medicaid Provider Agreement that a provider is required to sign to participate in the State of Iowa's Program requires a provider to agree to the following:  "1.4 To comply with all applicable Federal and State laws, rules and written policies of the Iowa Medicaid program, including but not limited to Title XIX of the Social Security Act (as amended), the code of Federal Regulations (CFR), the provisions of the Code of Iowa and rules of the Iowa Department of Administrative Services and written Department policies, including but not limited to, policies contained in the Iowa Medicaid Provider Manual, and the terms of this Agreement."  See Iowa Medicaid Provider Agreement, Form 470-2965, §1.4
Kansas	The Provider Agreement that a provider is required to sign to participate in the State of Kansas Program requires a provider to agree to the following terms and conditions:  "1. Rules, Regulations, Policies  The provider agrees to participate in the Kansas Medical Assistance Program (KMAP) and to comply with all applicable requirements for participation as set forth in federal and state statutes and regulations, and
	Program policies, within the authorities of such statutes and regulations, of the SRS Health Care Policy (HCP) as published in the KMAP Provider Manuals and Bulletins. The provider also agrees to comply with all state and federal laws and regulations applicable to services delivered and professional activities  14. Fraud
	The provider agrees that payment of claims is from federal and/or state funds and that any false claims, statements or documents or concealment of a material fact may be prosecuted under applicable federal or state laws. The provider acknowledges that the submission of a false claim, cost report, document or other false information, charging the recipient for covered services except for authorized spenddown and co-payment, and giving or taking of a kickback or bribe in relationship to covered services are crimes which are prosecutable under applicable federal and/or state laws. Among such applicable laws is K.S.A. 21-3844 et. seq. and amendments thereto (the Kansas Medicaid Fraud Control Act)."

See Kansas Medical Assistance Program Provider Agreement, §§ 1,14.

Kentucky	The Provider Agreement that a provider is required to sign to participate in Kentucky's Program requires a provider to agree to the following terms and conditions:
	"The Provider:
	(5) Assures awareness of the provisions of 42 U.S.C. § 1320a-7b and of the provisions of KRS 205.8451 to KRS 205.8483 relating to Medicaid Program Fraud and Abuse
	(7) Agrees [that] payment and satisfaction of claims will be from federal and state funds and that any false claims, statements, or documents or concealment or falsification of a material fact, may be prosecuted under applicable federal and state law."
	See Commonwealth of Kentucky Department for Medicaid Services Provider Agreement, §§4(5), 4(7)(c).
	In addition, the Provider Application that a provider is required to sign to participate in the Kentucky Program requires a provider to agree to the following terms and conditions:
	"I certify that I have read and understand the Medicaid Rules, Regulations, Policy and 42 U.S.C. § 1320a-7b to the best of my ability. I agree to abide by the Medicaid Program terms and conditions listed in this document"
	See Commonwealth of Kentucky Department for Medicaid Services and/or Kentucky Health Care Partnership Provider Application, at 10.
Louisiana	The Provider Agreement Enrollment Form that a provider is required to sign to participate in the State of Louisiana Program requires a provider to agree to the following terms and conditions:
	"5. I agree to abide by Federal and State Medicaid laws, regulations and program instructions that are applicable to the provider type for which I am enrolled. I understand that the payment of a claim by Medicaid is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions;"
	"6. I agree to conduct my activities/actions in accordance with the Medical Assistance Program Integrity Law as required to protect the fiscal and programmatic integrity of the medical assistance programs;"
	"13. I agree to adhere to the published regulations of the DHH Secretary and the Bureau of Health Services Financing, including, but not limited to, those rules regarding recoupment and disclosure requirements as specified in 42 CFR 455, Subpart B[.]"

See Enrollment Packet for the Louisiana Medical Assistance Program (PE-50, Addendum),  $\P$  5-6, 13.

Maine

The Provider Agreement that a provider is required to sign to participate in the State of Maine Program requires a provider to agree to the following terms and conditions:

- "1. Conditions of Participation. As a condition of participation or continued participation as a provider in MaineCare, the Provider agrees to comply with the provisions of the Federal and State laws and regulations related to Medicaid, the provisions of the MaineCare Benefits Manual....
- 2. Changes in Federal or State laws or Regulations.
  - a) Any change in Federal or State law or regulation that conflicts with or modifies any term of this Agreement will automatically become a part of this Agreement on the date such a change in statute or regulation becomes effective.
  - b) If the Provider objects to the application of the change in Federal or State law or regulation, it must notify the Department within thirty (30) calendar days of the effective date of the change that it will terminate the Agreement.... Failure to so notify the Department will be deemed acceptance of the change in law or regulation as part of this Agreement....

#### 5. Certification....

- b) The Provider ... certifies that at the time that this Agreement is executed neither it nor any of its employees, group members or agents has engaged in any activities prohibited by 42 U.S.C. § 1320a-7b....
- d) The Provider understands that engaging in activities prohibited by 42 U.S.C. § 1320a-7b may result in sanctions or termination of this Agreement, in accordance with applicable Federal and State laws and regulations."

See MaineCare/Medicaid Provider Agreement at A(1), (2), (5).

#### Massachusetts

The Provider Agreement that a provider is required to sign to participate in the Commonwealth of Massachusetts Program requires a provider to agree to the following terms and conditions:

"The Provider agrees . . . [t]o comply with all federal and state laws, regulations, and rules applicable to the Provider's participation in MassHealth, now existing or adopted during the term of this Provider Contract."

See MassHealth Provider Agreement ¶ II. B

#### Michigan

The Provider Agreement that a provider is required to sign to participate in the State of Michigan Program requires a provider to agree to the following terms and conditions:

"In applying for enrollment as a provider or trading partner in the Medical Assistance Program (and programs for which the Michigan Department of Community Health (MDCH) is the fiscal intermediary), I represent and certify as follows. . .

- 6. Before billing for any medical services I render, I will read the Medicaid Provider Manual from the Michigan Department of Community Health (MDCH). I also agree to comply with 1) the terms and conditions of participation noted in the manual, and 2) MDCH's policies and procedures for the Medical Assistance Program contained in the manual, provider bulletins and other program notifications.
- 7. I agree to comply with the provisions of 42 CFR 455.104, 42 CFR 455.105, 42 CFR 431.107 and Act No. 280 of the Public Acts of 1939, as amended, which state the conditions and requirements under which participation in the Medical Assistance Program is allowed.
- 13. I agree to comply with all policies and procedures of the Medical Assistance Program when billing for services rendered.

In pertinent part, the Michigan Medicaid Provider Manual states:

#### "8.2 RENDERING SERVICES

"All such services [Medicaid] rendered must be in compliance with the provider enrollment agreement; contracts (when appropriate); Medicaid policies; and applicable county, state, and federal laws and regulations governing the delivery of health care services."

See Michigan Department of Health and Human Services, Medicaid Provider Manual.

Minnesota	The Provider Agreement that a provider is required to sign to participate in the State of Minnesota Program requires a provider to agree to the following:  "[T]he Provider agrees to [c]omply with all federal and state statutes and rules relating to the delivery of services to Individuals and to the submission of claims for such services."
	See Minnesota Health Care Programs Provider Agreement, ¶ 2.
Mississippi	The Participation Agreement that a provider is required to sign to participate in the State of Mississippi Program requires a provider to agree to the following:
	"The Medicaid Provider agrees [t]o abide by federal and state laws and regulations affecting delivery of services."
	See Mississippi Medicaid Assistance Participation Agreement § C,1]2.104
Missouri	The Participation Agreement that a provider is required to sign to participate in the State of Missouri Program requires a provider to agree to the following terms and conditions:
	"1. [Provider] will comply with the Medicaid manual, bulletins, rules and regulations as required by the Division of Medical Services and the United States Department of Health and Human Services in the delivery of services and merchandise and in submitting claims for payment. I understand that in my field of participation I am not entitled to Medicaid reimbursement if I fail to so comply, and that I can be terminated from the program for failure to comply
	117. Medicaid participation under this agreement may be terminatedSuch reason(s) could include the provider being in violation of (c) rules regulations, policies or procedures of the Division of Medical Services The provider must be in compliance with all other applicable state or federal laws or regulations. Violation of any law or regulation may result in this agreement being terminated immediately upon mailing of written notice from the Division of Medical Services
	See Missouri Department of Social Services, Division of Medical Services Participation Agreement, 1, 7.

# Montana The Provider Agreement that a provider is required to sign to participate in the State of Montana Program requires a provider to agree to the following terms and conditions: "The Provider hereby agrees to comply with all applicable laws, rules and written policies pertaining to the Montana Medicaid Program (Medicaid). including but not limited to Title XIX of the Social Security Act, the Code of Federal Regulations (CFR), Montana Codes Annotated (MCA), Administrative Rules of Montana (ARM) and written Department of Public Health and Human Services (Department) policies, including but not limited to policies contained in the Medicaid provider manuals, and the terms of this document." See Montana Medicaid Provider Enrollment Agreement and Signature Page, Nebraska The Provider Agreement that a provider is required to sign to participate in the State of Nebraska's Program requires a provider to agree to the following terms and conditions: "I agree to participate as a provider in the Nebraska Medical Assistance Program, and assure the Nebraska Health and Human Services System: • That the policies and procedures of the Nebraska Health and Human Services System in the administration of the Nebraska Medical Assistance Program will be followed.... • That any false claims (including claims submitted electronically), statements, documents, or concealment of material fact may be prosecuted under applicable State or Federal laws (42 CFR 455.18).... I certify the information on this form is true, accurate, and complete." See Medical Assistance Provider Agreement, at 2.111 The policies and procedures of the Nebraska Medical Assistance Program include the following: "2-001.03 Provider Agreements: Each provider is required to have an approved agreement with the Department. By signing the agreement, the provider agrees to -1 Fully meet standards established by the federal Department of Health and Human Services, and any applicable state and federal laws governing the provision of their services....

Participation, at 1.

See Nebraska HHS Finance and Support Manual, Chapter 2-000 Provider

Nevada	The Provider Application that a provider is required to sign to participate in the State of Nevada Program requires a provider to agree to the following terms and conditions:  "I understand that I am responsible for the presentation of true, accurate and complete information on all invoices submitted to First Health Services. I further understand that payment and satisfaction of these claims will be from federal and state funds and that false claims, statements, documents, or concealment of material facts may be prosecuted under applicable federal and state laws."  See Provider Enrollment Application, at 6.
New Jersey	The Provider Agreement that a provider is required to sign to participate in the State of New Jersey Program requires a provider to agree to the following terms and conditions:  "Provider agrees:  (1) To comply with all applicable State and Federal laws, policies, rules and regulations"

#### New Mexico

The Provider Agreement that a provider is required to sign to participate in the State of New Mexico Program requires a provider to agree to the following terms and conditions:

The "Medicaid Provider Shall:

- 1.1 Abide by all federal, state, and local laws, rules, and regulations, including but not limited to those laws, regulations, and policies applicable to providers of medical services under Title XIX (Medicaid) and Title XXI (SCHIP) of the Social Security Act and other health care programs administered by HSD."
- "1.11 Submission of false claims or fraudulent representation may subject the provider to termination, criminal investigation and charges, and other sanctions specified in the MAD Provider Program Manual."
- "7.3 Provider status may be terminated immediately, without notice, in instances in which the health and safety of clients in institutions are deemed to be in immediate jeopardy; are subject to an immediate or serious threat; or when it has been demonstrated, on the basis of reliable evidence, that a provider has committed fraud, abuse[.)"

"BY SIGNATURE, THE PROVIDER AGREES TO ABIDE BY AND BE HELD TO All FEDERAL. STATE, AND LOCAL LAWS, RULES, AND REGULATIONS, INCLUDING, BUT NOT LIMITED TO THOSE APPLICABLE TO MEDICAID AND THOSE STATED HEREIN. BY SIGNATURE, THE PROVIDER SOLEMNLY SWEARS UNDER PENALTY OF PERJURY THAT THE INFORMATION GIVEN IS TRUE AND ACCURATE."

See New Mexico Provider Participation Agreement, at 3-6.

#### **New York**

The Provider Certification that a provider is required to sign to participate in the State of New York Program also requires a provider to agree to the following terms and conditions:

"As of [date of the certification], all claims submitted electronically or on paper to the State's Medicaid fiscal agent . . . will be subject to the following certification..."

"I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations...."

"All statements, data and information transmitted are true, accurate and complete to the best of my knowledge; no material fact has been omitted; I understand that payment and satisfaction of this claim will be from federal, state and local public funds and that I may be prosecuted under applicable federal and state laws for any violation of the terms of this certification including but not limited to false claims, statements or documents, or concealment of a material fact...."

"In submitting claims under this agreement I understand and agree that I (or the entity) shall be subject to and bound by all rules, regulations, policies, standards, fee codes and procedures of the New York State Department of Health and the Office of the Medicaid Inspector General as set forth in statute or title 18 of the Official Compilation of Codes, Rules and Regulation of New York State and other publications of the Department, including eMed NY Provider Manuals and other official bulletins of the Department."

See New York Certification Statement for Provider Billing Medicaid.

#### North Carolina

The Provider Agreement that a provider is required to sign to participate in the State of North Carolina Program requires a provider to agree to the following terms and conditions:

- A .1. "Comply with federal and state laws, regulations, state reimbursement plan and policies governing the services authorized under the Medicaid Program and this agreement (including, but not limited to, Medicaid provider manuals and Medicaid bulletins published by the Division of Medical Assistance and/or its fiscal agent)."
- B.1. "Payment of claims is from State, Federal and County funds and any false claims, false statements or documents, or misrepresentation or concealment of material fact may be prosecuted by applicable State and/or Federal law."
- C.6. "To not offer or provide any discount, rebate, refund, or any other similar unearned gratuity for the purpose of soliciting the patronage of Medicaid clients."

See North Carolina Division of Medical Assistance Medicaid Participation Agreement, at 3-5.131

In addition, North Carolina's Electronic Claims Submission (ESA) Agreement states:

"The Provider of Medical Care ("Provider") under the Medicaid Program in consideration of the right to submit claims by paperless means rather than by, or in addition to, the submission of paper claims agrees that it will abide by the following terms and conditions:

- 1. The Provider shall abide by all Federal and State statutes, rules, regulations and policies (including, but not limited to: the Medicaid State Plan, Medicaid Manuals, and Medicaid bulletins published by the Division of Medical Assistance (OMA) and/or its fiscal agent of the Medicaid Program, and the conditions set out in any Provider Participation Agreement entered into by and between the Provider and OMA.
- 2. Provider's signature electing electronic filing shall be binding as certification of Provider's intent to file electronically and its compliance with all applicable statutes, rules, regulations and policies governing electronic claims submission. The Provider agrees to be responsible for research and correction of all billing discrepancies. Any false statement, claim or concealment of or failure to disclose a material fact may be prosecuted under applicable federal and/or state law (P.L. 95-142 and N.C.G.S. 108A-63), and such violations are punishable by fine, imprisonment and/or civil penalties as provided by law.
- 5. . . . For purposes of compliance with this agreement and the laws, rules, regulations and policies applicable to Medicaid providers, the acts and/or omissions of Provider's staff or any entity acting on its behalf for electronic

submission of the Provider's claims shall be deemed those of the Provider, including any acts and/or omissions in violation of Federal and State criminal and civil false claims statutes . . . .

The undersigned having read this Agreement for billing Medicaid claims electronically and understanding it in its entirety, hereby agree(s) to all of the stipulations, conditions, and terms stated herein.

North Carolina Department of Health And Human Services Division of Medical Assistance Electronic Claims Submission (ECS) Agreement, at 1-3 It further states:

"By signature below, I understand and agree that non-electronic Medicaid claims may be submitted without signature and this certification is binding upon me for my actions as a Medicaid provider, my employees, or agents who provide services to Medicaid recipients under my direction or who file claims under my provider name and identification number.

I certify that all claims made for Medicaid payment shall be true, accurate, and complete and that services billed to the Medicaid Program shall be personally furnished by me, my employees, or persons with whom I have contracted to render services, under my personal direction.

I understand that payment of claims will be from federal, state and local tax funds and any false claims, statements, or documents or concealment of a material fact may be prosecuted under applicable Federal and State laws and I may be fined or imprisoned as provided by law."

*See* North Carolina Division of Medical Assistance, Provider Certification for Signature on File.

#### Ohio

The Provider Agreement that a provider is required to sign to participate in the State of Ohio Program requires a provider to agree to the following terms and conditions:

"This provider agreement is a contract between the Ohio Department of Job and Family Services (the Department) and the undersigned provider of medical assistance services in which the Provider agrees to comply with the terms of this provider agreement, state statutes, Ohio Administrative Code rules, and Federal statutes and rules...."

See Ohio Health Plans Provider Enrollment Application/Agreement at 13.

#### Oklahoma

The Provider Agreement that a provider is required to sign to participate in the State of Oklahoma Program requires a provider to agree to the following terms and conditions:

- 4.1 "(c) Provider agrees to comply with all applicable Medicaid statutes, regulations, policies, and properly promulgated rules of OHCA...."
- 4.2 "(e) Satisfaction of all claims will be from federal and state funds. Any false claims, statements, or documents, or any concealment of a material fact may be prosecuted under applicable federal or state laws."
- "5.0 The parties to this Agreement acknowledge and expect that over the term of this Agreement laws may change. Specifically, the parties acknowledge and expect (i) federal Medicaid statutes and regulations, (ii) state Medicaid statutes and rules, (iii) state statutes and rules governing practice of health-care professions, and (iv) any other laws cited in this contract may change. The parties shall be mutually bound by such changes."
- §5.2 "Provider shall comply with and certifies compliance with: . . .
- p) The Federal False Claims Act, 31 U.S.C. §3729-3733; 31 U.S.C. 3801."

See Oklahoma Health Care Authority Agreement.

## Oregon

The Provider Agreement that a provider is required to sign to participate in the State of Oregon Program requires a provider to agree to the following terms and conditions:

"D. Compliance with applicable laws... Provider shall comply with federal, state and local laws and regulations applicable to this Enrollment Agreement, including but not limited to OAR 410-120-1380. OMAP's obligations under this Enrollment Agreement are conditioned upon Provider's compliance with provisions of ORS 279.312,279.314, 279.316, 279.320, and 279.555, as amended from time to time, which are incorporated in this agreement. Provider is responsible for all Social Security payments and federal or state taxes applicable to payments under this Enrollment Agreement."

See OMAP Provider Application, §D.

Pennsylvania	The Provider Agreement that a provider is required to sign to participate in the Commonwealth of Pennsylvania Program requires a provider to agree to the following terms and conditions:
	"A. The Provider agrees to participate in the Pennsylvania Medical Assistance Program (the 'Program'), and in the course of such participation to comply with all federal and Pennsylvania laws generally and specifically governing participation in the Program. The foregoing include but are not limited to: 42 U.S.C. § 1396 et seq., 62 P.S.§§ 441-451,42 C.F.R. §§431-481 and the regulations adopted by the Department of Public Welfare (the 'Department'). The Provider agrees to be knowledgeable of and to comply with applicable rules, regulations, rates and fee schedules promulgated under such laws and any amendments thereto."
	See Pennsylvania Provider Agreement, § 1(A).
Rhode Island	The Provider Agreement that a provider is required to sign to participate in the State of Rhode Island Program requires a provider to agree to the following terms and conditions:  "I, the Provider with the understanding that participation in the Rhode Island Executive Office of Health and Human Services Medical Assistance Program hereafter, "EOHHS" or "RIMAP" is voluntary, agrees to the following:
	1. To follow all laws, rules, regulations, certification standards, policies and amendments including but not limited to the False Claims Act and HIPPA, that govern the Rhode Island Medical Assistance Program as specified by the Federal Government and the State of Rhode Island. Suspected violations must be reported by the Provider to EOHHS, its fiscal agent, or the Medicaid Fraud Control Unit of the Rhode Island Attorney General's Office."
	See Rhode Island Executive Office of Health and Human Services Provider Agreement Form, at 1.

#### **South Carolina**

The Medicaid Enrollment form that a provider is required to sign to participate in the State of South Carolina Program requires a provider to agree to the following terms and conditions:

- "• That all services rendered and claims submitted shall be in compliance with all applicable federal and state laws and regulations and in accordance with SCDHHS policies, procedures and Medicaid Provider Manuals.
- That all information provided on the Medicaid enrollment form is incorporated as part of this agreement.
- That Medicaid reimbursement (payment of claims) is from state and federal funds and that any falsification (false claims, statement or documents) or concealment of material fact may be prosecuted under applicable state and federal laws."

See South Carolina Medicaid Enrollment Agreement at 1-2.

In addition, in 2010, the State of Carolina added the following additional term and condition:

"I agree to abide by the Medicaid laws, regulations and program instructions that that apply to me or to the organization. The Medicaid laws, regulations, and program instructions are available through SCDHHS. I understand that payment of a claim by Medicaid is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions, and on the provider's compliance with all applicable conditions of participation in Medicaid."

See South Carolina Medicaid Enrollment Agreement, at 1-2.

#### **Tennessee**

One of the Provider Agreements that a provider was required to sign to participate in the State of Tennessee Program requires a provider to agree to the following terms and conditions:

C. TENNCARE Provider Agreement Requirements...

42. The Provider, Subcontractor or any other entity agrees to abide by the Medicaid laws, regulations, and program instructions that apply to the Provider. The Provider, Subcontractor or any other entity understands that payment of a claim by TENNCARE or a TENNCARE Managed Care Contractor and/or Organization is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, federal anti-kickback statute, the Stark law, and federal requirements on disclosure, debarment and exclusion screening), and is conditioned on the Provider's, Subcontractor's, or any other entity's compliance with all applicable conditions of participation in Medicaid. The Provider, Subcontractor, or any other entity understands and agrees that each claim the Provider, Subcontractor, or any other entity submits to TENNCARE or a TENNCARE managed contractor, and/or Organization constitutes a certification that the Provider, Subcontractor, or any other entity has complied with all applicable Medicaid laws, regulations and program instructions (including, but not limited to, the federal antikickback statute and the Stark law and federal requirements on disclosure, debarment and exclusion screening), in connection with such claims and the services provided therein.

Tennessee Volunteer State Health Plan Provider Administration Manual, XII (C). ¶ 42.

#### **Texas**

The Provider Agreement that a provider is required to sign to participate in the State of Texas Program requires a provider to agree to the following terms and conditions:

"As a condition for participation as a provider under the Texas Medical Assistance Program (Medicaid), the provider (Provider) agrees to comply with all terms and conditions of this agreement.

#### I. ALL PROVIDERS

1.1 Agreement and documents constituting Agreement.

Provider has a duty to become educated and knowledgeable with the contents and procedures contained in the Provider Manual. Provider agrees to comply with all of the requirements of the Provider Manual, as well as all state and federal laws governing or regulating Medicaid, and provider further acknowledges and agrees that the provider is responsible for ensuring that all employees and agents of the provider also comply. Provider agrees to acknowledge HHSC's provision of enrollment processes and authority to make enrollment decisions as found in Title 1, Part 15, Chapter 352 of the Texas Administrative Code. Provider is specifically responsible for ensuring that the provider and all employees and agents of the Provider comply with the requirements of Title 1, Part 5, Chapter 371 of the Texas Administrative Code, related to waste, abuse and fraud, and provider acknowledges and agrees that the provider and its principals will be held responsible for violations of this agreement through any acts or omissions of the provider, its employees, and its agents."

"1.2.3. This Agreement is subject to all state and federal laws and regulations relating to fraud, abuse and waste in health care and the Medicaid program."

## "XI ACKNOWLEDGMENTS AND CERTIFICATIONS

- 11.1 By signing below, Provider acknowledges and certifies to all of the following...
- (g) Provider agrees to abide by all Medicaid regulations, program instructions, and Title XIX of the Social Security Act. The Medicaid laws, regulations, and program instruction are available through the Medicaid contractor. Provider understands that payment of a claim by Medicaid is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicaid."

Virginia	The Provider Agreement that a provider is required to sign to participate in the Commonwealth of Virginia Program requires a provider to agree to the following terms and conditions:  "8. The provider agrees to comply with all applicable state and federal laws, as well as administrative policies and procedures of VMAP as from time to time amended."  See Commonwealth of Virginia Department of Medical Assistance Services Medical Assistance Program Participation Agreement, at 1.
Washington	The Provider Agreement that a provider is required to sign to participate in the State of Washington Program requires a provider to agree to the following terms and conditions:  "The Provider is subject to and shall comply with all federal and state laws, rules, and regulations and all program policy provisions, including department numbered memoranda, billing instructions, and other associated written department issuances in effect at the time the service is rendered, which are incorporated into this Agreement by this reference."  See Washington Core Provider Agreement (DSHS 09-048), ¶ 1.
West Virginia	The Provider Enrollment Application that a provider is required to sign to participate in the State of West Virginia Program requires a provider to agree to the following terms and conditions:  "1. The Provider hereby agrees to comply with all applicable laws, rules and written policies pertaining to the West Virginia Medicaid Program (Medicaid), including but not limited to Title XIX and Title XXI (Children's Health Insurance) of the Social Security Act, the Code of Federal Regulations, the West Virginia State Plan, the Department of Health and Human Resources Bureau for Medical Services (Department/Bureau), written manuals, program instructions, policies and this document  I understand that payment of any claims will be from Federal and State funds, and that any falsification, or concealment of a material fact may be prosecuted under Federal and State laws."  See West Virginia Medicaid Provider Enrollment Agreement.

## Wisconsin

The Provider Agreement that a provider is required to sign to participate in the State of Wisconsin Program requires a provider to agree to the following terms and conditions:

"2. Provider acknowledges that certain terms, conditions, and restrictions that are either listed in this section, set forth in applicable law, or available to the Provider through Wisconsin Medicaid govern its participation as a provider in Wisconsin Medicaid, and that by submitting claims as a Wisconsin Medicaid provider, the Provider becomes subject to those terms, conditions, and restrictions. Some of these terms, conditions, and restrictions are set forth in Internet-based provider handbooks, bulletins, and periodic updates regarding changes in state or federal law, policy, reimbursement rates and formulas, departmental interpretation, and procedural directives such as billing and prior authorization procedures, and specific reimbursement changes, which are issued by the DHS under ch. DHS 108.02(4), Wis. Admin. Code.

These handbooks, bulletins, and periodic updates are available to the Provider through the Forward Health Portal at www.forwardhealth.wi.gov/, or by contacting Wisconsin Medicaid Provider Services at (800) 947-9627. The omission of any applicable term, conditions, or restriction from this section does not excuse the Provider from complying with that term, condition, or restriction. The Provider further acknowledges that all applicable terms, conditions, and restrictions govern the Provider's participation in Wisconsin Medicaid, regardless whether the Provider has actual knowledge of those terms, conditions, and restrictions."

- "4. . . . This Agreement and Acknowledgment remains in effect as long as the Provider is certified to participate in Wisconsin Medicaid."
- "5. The Provider acknowledges that any statement made in this document or in the provider application process constitutes a statement or representation of a material fact knowingly and willfully made or caused to be made by Provider in an application for a benefit or payment, or made for use in determining rights to such benefit or payment, that is, within the meaning of s. 49.49(1) and (4m), Wis. Stats., which, if false, subjects the Provider to criminal or other penalties."

See Wisconsin Medicaid Provider Agreement and Acknowledgment of Terms of Participation.

65. TRICARE (formerly known as CHAMPUS) is part of the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active

duty beneficiaries, including dependents of active duty personnel, and military retirees and their dependents. The military health system, which is administered by the Department of Defense ("DOD"), is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program known as TRICARE. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

- 66. TRICARE prescription drug benefits are provided through three different programs: military treatment facility outpatient pharmacies, TRICARE network retail pharmacies, and TRICARE's mail order service. TRICARE contracts with a PBM to administer its retail and mail order pharmacy programs. In addition, TRICARE beneficiaries can also pay out-of-pocket to fill prescriptions at non-network retail pharmacies and submit a claim for reimbursement directly with TRICARE's PBM. The claims process is different for each of these pharmaceutical programs.
- 67. When a TRICARE beneficiary brings a prescription to a TRICARE network retail pharmacy, for example, the pharmacy submits an electronic claim to the PBM for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary's TRICARE coverage, and, if the prescription claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a 10-day hold to ensure the prescription was picked up and not returned to the shelf by the pharmacy, the PBM sends a TRICARE Encounter Data ("TED") record electronically to TRICARE. The TED record includes information regarding the prescription event, including the reimbursement amount to be paid to the

dispensing pharmacy. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from the Federal Reserve Bank ("FRB"). The FRB then transfers funds to the PBM's bank account.

- 68. If the prescription is filled at a non-network retail pharmacy, the beneficiary must pay the full price of the prescription to the pharmacist and file a claim for reimbursement on DD Form 2642, TRICARE/DoD.CHAMPUS Medical Claim Patient's Request for Medical Payment ("Form 2642"). The Form 2642 is mailed to the PBM. As in the case of reimbursements under the retail pharmacy program, a TED record is created and sent to TRICARE. TRICARE then authorizes payment to the TRICARE beneficiary. Upon receiving that authorization, the PBM issues a check to the beneficiary, which is drawn on the PBM's bank account. TRICARE then reimburses the PBM in the same manner as it does under the retail pharmacy program, such that funds are transferred from the FRB to the PBM's bank account.
- 69. TRICARE beneficiaries can also fill prescriptions through TRICARE's mail order pharmacy program as well. TRICARE beneficiaries submit prescriptions by mail, fax, or electronically to TRICARE's PBM, along with any co-pay (if applicable). TRICARE's PBM delivers the prescription to the beneficiary via free standard shipping. The medications dispensed through the mail order pharmacy program are filled from the PBM's existing inventory of pharmaceuticals. The PBM then requests replenishment pharmaceuticals from the DOD's national prime vendor contracted by Defense Logistics Agency ("DLA"). The DOD procures the pharmaceuticals through its national prime vendor and replenishes the PBM's inventory of pharmaceuticals after accumulated dispensings reach full package size amounts.

The PBM then submits a TED record to TRICARE to obtain administrative fees in connection with that prescription event. The DLA bills TRICARE directly for drug replenishment costs.

- 70. Pursuant to 38 U.S.C. §8126, pharmaceutical manufacturers are required to enter into national contracts with the DOD pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as at least 24% less than the manufacturer's average price based on all sales to commercial customers through a wholesaler or distributor). Pursuant to the DOD's contract with its national prime vendor, the national prime vendor submits an invoice to the DOD for payment of pharmaceuticals supplied to the PBM in connection with the mail order pharmacy program, charging the DOD the price set by the contract awarded by the DOD to the drug manufacturer.
- 71. Since March 2003, TRICARE has contracted with a pharmacy benefits manager, Express Scripts, Inc. ("ESI"), to administer TRICARE's mail order pharmacy programs. ESI has also administered TRICARE's retail pharmacy program since June 2004.
- 72. Similarly, TRICARE's military treatment facilities purchase medications through procurement contracts with third party pharmaceutical prime vendors. When a TRICARE beneficiary submits an outpatient prescription to a military treatment facility's outpatient pharmacy, the pharmacy purchases the medication from the prime vendor pursuant to an existing procurement contract, and the drug is then dispensed to the patient.
- 73. While some physicians enroll in the TRICARE program as network or participating providers, any physician that is licensed, accredited and meets other standards of the medical community is authorized to provide services to TRICARE beneficiaries. Physicians who are enrolled in the TRICARE network must expressly certify their compliance with TRICARE's regulations and all providers that offer services to TRICARE beneficiaries, whether

network providers or non-participating providers, are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R. §199.9(a)(4).

74. TRICARE's Reimbursement Manual (6010.58-M, February 1, 2008), provides the following with respect to the "Reimbursement Of Covered Services Provided By Individual Health Care Professionals And Other Non-Institutional Health Care Providers":

Services provided by individual professional providers of care and other non-institutional health care providers are to be billed only on the CMS 1500 Claim Form or the TRICARE 2642 for payment. Individual health care professionals (e.g., physicians) and non-institutional providers (e.g., suppliers) are to use the CMS 1500 Claim Form. Institutional providers (e.g., hospitals) are to use the CMS 1500 Claim Form or the CMS 1450 UB-04 (if adequate Common Procedure Terminology (CPT) coding information is submitted) to bill for the professional component of physicians and other authorized professional providers. Beneficiaries (or their representatives) who complete and file their own claims for individual health care professional and other non-institutional health care provider services may want to use the TRICARE 2642 claim form for payment.

See Chapter 1, Section 7 at 3.1.3.

75. TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. 32 C.F.R. §199.9(b). Kickback arrangements are included within the definition of abusive situations that constitute program fraud. *Id.* §§199.2(b),<sup>4</sup> 199.9(c)(12).<sup>5</sup> Likewise, TRICARE's program regulations specifically provide that providers "have a duty to familiarize themselves with, and comply with, the program requirements," while

<sup>&</sup>lt;sup>4</sup>32 C.F.R. §199.2(b), defines "fraud" as follows: "For purposes of this part, fraud is defined as (1) a deception or misrepresentation by a provider, beneficiary, sponsor, or any person acting on behalf of a provider, sponsor, or beneficiary with the knowledge (or who had reason to know or should have known) that the deception or misrepresentation could result in some unauthorized CHAMPUS benefit to self or some other person, or some unauthorized CHAMPUS payment, or (2) a claim that is false or fictitious, or includes or is supported by any written statement which asserts a material fact which is false or fictitious, or includes or is supported by any written statement that (a) omits a material fact and (b) is false or fictitious as a result of such omission and (c) is a statement in which the person making, presenting, or submitting such statement has a duty to include such material fact. It is presumed that, if a deception or misrepresentation is established and a CHAMPUS claim is filed, the person responsible for the claim had the requisite knowledge. This presumption is rebuttable only by substantial evidence. It is further presumed that the provider of the services is responsible for the actions of all individuals who file a claim on behalf of the provider (for example, billing clerks); this presumption may only be rebutted by clear and convincing evidence."

<sup>&</sup>lt;sup>5</sup>32 C.F.R. 199.9(c)(12) specifically provides that "[f]or the definition of fraud, see § 199.2 of this part" and "[e]xamples of situations which, for the purpose of this Part, are presumed to be fraud include, but are not limited to: ... [a]rrangements by providers with employees, independent contractors, suppliers, or others which appear to be designed primarily to overcharge

contractors and peer review organizations "have a responsibility to apply provisions of this regulation in the discharge of their duties, and to report all known situations involving fraud, abuse, or conflict of interest." *Id.* §§199.9(a)(4), (5).

- 76. The regulations of TRICARE and its predecessor, CHAMPUS, have established at all pertinent times that claims tainted by kickbacks are presumed to be fraudulent in nature and, as a result, should not be submitted by providers for reimbursement.
- 77. CMS-1500 currently requires the following certification by physicians and Suppliers as a pre-condition of payment:

In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law); 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE; 6) for each service rendered incident to my professional service, the identity (legal name and NPI, license #, or SSN) of the primary individual rendering each service is reported in the designated section. For services to be considered "incident to" a physician's professional services, 1) they must be rendered under the physician's direct supervision by his/her employee, 2) they must be an integral, although incidental part of a covered physician service, 3) they must be of kinds commonly furnished in physician's offices, and 4) the services of non-physicians must be included on the physician's bills.

For TRICARE claims, I further certify that I (or any employee) who rendered services am not an active duty member of the Uniformed Services or a civilian employee of the United States Government or a contract employee of the United States Government, either civilian or military (refer to 5 USC 5536). For Black -Lung claims, I further certify that the services performed were for a Black Lung-related disorder.

52

the CHAMPUS through various means (such as commissions, fee-splitting, and kickbacks) used to divert or conceal improper or unnecessary costs or profits."

No Part B Medicare benefits may be paid unless this form is received as required By existing law and regulations (42 CFR 424.32).

NOTICE: Any one who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.

See CMS Form 1500 at 2 (02/12).6

- 78. <u>Veterans Administration Health Care</u>. The Department of Veterans Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are procured directly by the VA. A VA beneficiary can take a prescription to a VA medical facility, at which point the VA dispenses the medication to the VA beneficiary from its existing inventory. The VA also supports a mail service prescription program as part of its outpatient drug benefit. VA beneficiaries can submit prescriptions to that mail service program, and the VA then dispenses pharmaceuticals purchased by the VA directly to VA beneficiaries. The VA medical system serves approximately four million veterans.
- 79. The VA purchases the pharmaceuticals that it dispenses at its medical facilities and through its mail service prescription program through its Federal Supply Schedule ("FSS") program. Pursuant to 38 U.S.C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the VA, pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as 26% less than the manufacturer's average price based on all sales to commercial customers through a wholesaler or distributor). A VA facility that requires a supply of a particular medication (including a mail order facility) submits a purchase order to the VA's pharmaceutical prime vendor ("PPV") for distribution of pharmaceuticals. Since May 10, 2004, McKesson

<sup>&</sup>lt;sup>6</sup>Medicare and other Government Healthcare Programs began accepting Form CMS-1500 (02/12) on January 6, 2014, and fully replaced the prior Form CMS-1500 (08/05) on April 1, 2014. Express certification claims are only asserted in this Complaint in connection with the submission of Form CMS-1500 (02/12).

Corporation has served as the VA's PPV. The PPV fills the order for the facility, and then submits an invoice to the VA for payment, charging the VA the price set by the contract awarded by the VA to the drug manufacturer. The VA makes payment to the PPV. The PPV then seeks a chargeback from the drug manufacturer for any difference between the contract price paid by the VA and the PPV's acquisition price.

- 80. To the best of Plaintiffs-Relators' knowledge, information and belief, the VA awarded TEVA a contract that requires TEVA to comply with all applicable federal, state and local laws, executive orders, rules and regulations applicable to performance of TEVA's duties under that VA contract.
- 81. <u>Pricing Violations</u>. Pharmaceutical manufacturers participating in Medicaid programs must rebate to the States, a certain statutorily-prescribed portion of the price of drugs purchased by each Medicaid program in each state. 42 U.S.C. § 1396r-8(a)(1). Manufacturers do this because the Medicaid statute, 42 U.S.C. §§1396a-u, permits the Federal Government to partially reimburse States only for drugs purchased from manufacturers who have agreed to pay statutorily specified rebates to those States. 42 U.S.C. §1396r-8. Thus, pharmaceutical manufacturers that want their drugs available to Medicaid beneficiaries under the Medicaid program enter into a Rebate Agreement with HHS to provide such rebates. 42 U.S.C. § 1396r-8(a)(1).
- 82. The Rebate Agreement requires manufacturers to submit a Quarterly Report (Form CMS-367). The Quarterly Report includes information regarding each of the manufacturer's "Covered" Drugs, including such information as its "Average Manufacturer Price" ("AMP"), "Baseline AMP," and its "Best Price." Based upon this information, HHS,

through its component agency, CMS then informs the States of the rebate which they are entitled to collect with respect to each drug.

- 83. Defendant entered into a Rebate Agreement with HHS. In that Agreement, Defendant agreed to comply with 42 U.S.C. §1396r-8, and therefore:
- a. Agreed to report its Best Price, inclusive of cash discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, etc.;
- b. Agreed that it would determine its Best Price based upon its AMP, calculated as "net sales divided by numbers of units sold, excluding free goods (*i.e.*, drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include that in the calculation, cash discounts and all other price reductions "which reduce the actual price paid"; and
- c. Agreed that the Best Price would not take into account nominal prices, defined as prices that are less than 10 percent of the AMP in that quarter, so long as the sale of product at a nominal price was not contingent on any other sale.
- 84. After execution of this Agreement, Defendant reported its AMP and/or Best Price in each quarter, to the Medicaid Program on an electronic form of Form CMS-367.
- 85. As alleged herein, Defendant failed to take into account the kickbacks it paid when reporting its Best Price.
- As a result, Defendant's Best Price, for quarterly reports submitted for at least the past six years, were inflated, which reduced the percentage difference between AMP and Best Price, thereby reducing the rebate amount that Defendant ultimately paid to each State Medicaid program. Defendant artificially inflated its Best Price, by calculating its Best Price without taking into account its inducement activities alleged in this Complaint, which reduced the true

cost of its drugs. Defendant knowingly set and reported its Best Price for these drugs at levels far higher than the actual Best Price, in Form CMS-367, submitted quarterly to CMS for at least the past six years. By doing so, Defendant has violated the FCA (and applicable state False Claims Acts), by knowingly making, using, or causing to be made or used, a false record to conceal, avoid, or decrease an obligation to pay or transmit money to federal and state governments.

- 87. Under the Veterans Healthcare Act of 1992 ("VHCA"), drug manufacturers are required to enter a pricing agreement with HHS for the section 340B Drug Pricing Program, and with the VA and other DOD programs.
- 88. Once a labeler/manufacturer enters into such a pricing agreement, its drugs are listed on the Federal Supply Schedule ("FSS"), a price list containing more than 20,000 pharmaceutical products. The VA and other Government Healthcare Programs depend on the FSS for most of their drug purchases, with the exception of several national contracts awarded for specific drugs considered to be therapeutically interchangeable.
- 89. Under the VHCA, drug manufacturers must comply with 38 U.S.C. § 8126. Subsection (a)(2) requires that "the price charged during the one-year period beginning on the date on which the agreement takes effect may not exceed 76 percent of the non-Federal average manufacturer price (less the amount of any additional discount required under subsection (c)) ...." As alleged herein, Defendant failed to take into account its inducements when reporting the non-federal average manufacturer price. Defendant therefore violated 38 U.S.C. § 8126, causing damage to the VA program and, by not giving its best price as set forth in subsection (a)(2), Defendant became ineligible for Medicare and other Government Healthcare Program reimbursement.

- 90. Approximately 25-30% of all patients suffering from Multiple Sclerosis ("MS") are on Medicare. As a result, approximately 25-30% of all prescriptions for Copaxone (one of the Covered Drugs described below) are reimbursed by the Medicare program, which amounts to over \$500 million per annum in Medicare reimbursement alone.
- 91. Over 50% of all patients suffering from Parkinson's Disease ("PD") are on Medicare. As a result, over 50% of all prescriptions for Azilect (one of the Covered Drugs described below) are reimbursed by the Medicare program, which amounts to over \$150 million per annum in Medicare reimbursement alone.
- 92. TEVA carefully tracks the number of lives (*i.e.*, people) covered by each of the Government Healthcare Programs, their coverage of the Covered Drugs and the amount they reimburse for the Covered Drugs, and assist physicians and other providers in targeting patients who are covered by Government Healthcare Programs in light of the high costs of the Covered Drugs, as described below.

## IV. THE COVERED DRUGS

- 93. Copaxone® (glatiramer acetate injection) is TEVA's largest and first major branded drug. It was approved by the FDA in 1996. Copaxone® is indicated for the reduction of the frequency of relapses in relapsing-remitting MS. The average annual cost for a Medicare and/or Medicaid patient taking Copaxone® is approximately \$60,000, having risen from less than \$10,000 per year when the drug was first launched almost 20 years ago. TEVA has Orange Book-listed patents relating to Copaxone®, which expired in May 2014, as well as a non-Orange Book patent expiring in September 2015.
- 94. Azilect® (rasagiline tablets) is TEVA's second in-house developed drug and was approved by the FDA in 2006. Azilect® is used to treat many of the symptoms of PD. A

Medicare and/or Medicaid patient's annual average cost of taking Azilect® is approximately \$4,600. TEVA has several patents relating to Azilect® that have or will expire between 2013 and 2027.

- 95. Copaxone® and Azilect® are considered by TEVA to be the leading drugs within its Central Nervous System portfolio.
- 96. Since 2008, Copaxone® has been the market leader in its therapeutic class, with a U.S. market share of approximately 40%. Between 2010 and 2012, TEVA's sales for Copaxone® have been enormous: \$2.958 billion in 2010; \$3.570 billion in 2011; and \$3.996 billion in 2012.
- 97. Like Copaxone®, sales for Azilect® have steadily risen, from \$244 million in 2010 to \$290 million in 2011, and to \$330 million in 2012.
- 98. With patents relating to Copaxone® and Azilect® set to expire soon, TEVA has pushed aggressively to increase the market share for these Covered Drugs by paying doctors to prescribed these drugs. As set forth below, speaker programs served as TEVA's "silver bullet" for doing just that.

# V. <u>SUBSTANTIVE ALLEGATIONS</u>

## A. <u>TEVA's Illicit Kickbacks Through Pretextual Speaker Programs</u>

- 99. The increased sales of the Covered Drugs are hardly a coincidence they are the direct result of a pervasive illegal kickback scheme whereby TEVA paid physicians to write prescriptions for the Covered Drugs through an elaborate and widespread network of paid speaker programs.
- 100. TEVA organizes, schedules, and tracks its speaker programs primarily through Allied Health Media ("AHM"). In addition, local speaker programs were previously scheduled

and tracked through TEVA's Local Speaker Program Portal ("LSPP"). Prior to 2010, sales representatives executed and created check requests via the "Check Request System" on TEVA's intranet site. From approximately 2010 to 2011, sales representatives used both the LSPP and AHM program management systems. The LSPP ended in 2011. As of 2012, AHM has been the only scheduling method used for speaker programs.

- speaker program, which payments are disguised as "honorarium" so that TEVA can feign compliance with federal, state, and city kickback laws. Prior to 2011, TEVA sales representatives were permitted to decide the amount that they paid physicians to speak about the Covered Drugs, which TEVA sales representatives delivered to such speakers in green envelopes to emphasize the lucrative nature of serving as a speaker. Since at least 2006, TEVA has used speaker programs as the means to pay physicians to prescribe Copaxone® and Azilect® and build the market share of and the number of prescriptions written for these Covered Drugs. Confirming the explicit nature of the quid pro quo relationship, physicians were only permitted to remain as paid speakers if they increased the number of prescriptions written for the Covered Drugs (or at least continued to write a significant number of prescriptions).
- In 2011, the total number of speaker programs for the Covered Drugs was 1,329. In 2012, this number increased nearly four-fold, to 5,036. As of August 2013, approximately 4,600 programs had been completed or scheduled, with approximately 420 trained Copaxone® speakers and 410 trained Azilect® speakers. In 2013, certain physicians spoke an alarming 42, 56, 60, and 80 times. These figures reflect only AHM speaker programs and do not include LSPP speaker programs. If they did, the figures would be even higher. The "honorariums" (*i.e.*, the amount paid to physicians) associated with these speaker programs average between \$2,000

and \$2,500 per program. As a result, in 2012 alone, Teva paid more than \$10 million to physicians for "speaking" at these programs and spent even more in 2013 and 2014. Indeed, at TEVA's Central Area Sales Meeting held in Chicago, Illinois in October 2013, Central Area Director, Gary Smith, crowed that 80% of all Azilect® prescriptions currently are written by Azilect® paid speakers. Not only did Mr. Smith stress the need to continue paying physicians to speak (since it results in the physicians themselves writing more prescriptions), he reinforced TEVA's intent to increase its use of payments to speakers as a way to drive even greater sales in 2014.

- 103. Although TEVA purports to abide by the guidelines developed in the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals ("the PhRMA Code") issued in 2004 and reissued in 2009, as referenced in its corporate compliance materials, the fact of the matter is that TEVA has consistently flaunted the requirements of the PhRMA Code. In addition, TEVA did not complete any needs-assessments or similar evaluations before adding paid speakers. Instead, TEVA added paid speakers on the basis of return on investment ("ROI") analysis, which specifically related to the fact that paid speakers were more likely to prescribe the Covered Drugs or increase their prescriptions of the Covered Drugs. The fact that over 80% of Azilect prescriptions are written by paid speakers confirms the true nature of TEVA's paid speaker program.
- 104. Beginning in approximately 2003, TEVA began using "preceptorship" programs as a means to pay speakers for prescribing the Covered Drugs, and this tactic continued until approximately 2010. "Preceptorship" programs were programs in which physicians were paid to allow a TEVA sales representative to spend time observing their practice when, in fact, the sole purpose of the payments was to compensate physicians. As the use of preceptorship programs

fell into disfavor (as a result of their blatantly fraudulent nature), the use of speaker programs, including "Journal Clubs," became more prevalent beginning in or about 2008 and 2009, because these programs could be more easily disguised as purportedly legitimate when, in fact, they also were entirely fraudulent in nature because the same journal presentations occurred again and again to the same attendees.

TEVA's speaker programs more recently have principally taken the form of 105. recurring "Peer-to-Peer Programs" and "Patient Programs" that, inter alia, had few to no attendees, lacked little, if any, educational value, discussed dated and/or redundant topics, were conducted by multiple speakers from the same medical groups, and were often attended by the same physicians, patients and their families. Indeed, for Copaxone® programs, the same two topics were repeatedly presented – "The Current RRMS Landscape and Available Therapies" and "Navigating Options in RRMS" – and, for Azilect® programs, the same four topics were also repeatedly presented – "Dopamine Management in Early to Moderate-to-Advanced Parkinson's Disease: A Case Study Approach," "The Continuum of Parkinson's Disease Treatment: Enhancing Patient Care: Initial Treatment of Early PD," "Azilect® as Add-on Therapy in Parkinson's Disease," and "Managing Parkinson's Disease: The Role of Azilect®." This is, unsurprisingly, because neither of the Covered Drugs is new to the market – they have been on the market, respectively, for 18 and 8 years with virtually no therapeutic changes or advances with respect to the Covered Drugs or the literature available with respect to the Covered Drugs -- and there have been little, if any, changes in the indications appropriate for the Covered Drugs and no material changes in the indications for the Covered Drugs. TEVA attempted to disguise the fact that the same presentations were being given again and again to the same attendees by (a) changing the titles of the programs slightly without changing the substance of the presentations, (b) changing the wording in the presentations without making any material or substantive changes to the presentations, and (c) shuffling the "slide deck" so that the presentation appeared somewhat different – even though the substance was the same. Indeed, the only new material presented by "speakers" regarding the Covered Drugs was unlawful, "off-label" information presented by the physician-speakers, the dissemination of which TEVA explicitly and implicitly approved.

- 106. As detailed herein, it was common for physicians to rotate between serving as speakers and attendees to disguise the fraudulent nature of these programs and because it often was difficult, if not impossible, to persuade practitioners to attend events in which it was known that the physician-speaker had no new, material information to offer regarding the Covered Drugs.
- changed over time in minor respects, those changes were not material. Specifically, the core content of the two Copaxone® programs essentially stayed the same, including: (a) drug background information such as how long Copaxone® has been on the market; (b) Copaxone® safety profile; efficacy information; (c) how Copaxone® is used and administered; and (d) its side effects. The changes to the Copaxone® programs were limited to presentation slides with different titles and layouts, or with additional references to newly-approved and pipeline MS therapies. The same is true for the foregoing Azilect® programs. Although those programs changed with respect to the title, layout, and order of presentation slides, the core content for the Azilect® programs stayed the same, including information relating to: (a) mode of action; (b) L-Dopa studies; (c) side effects; (d) dosing; (e) wearing off; and (f) dopamine management. In sum, there were no significant or material changes in the programs related to the Covered Drugs,

and the same core material was presented over and over again. Indeed, the only reason that these changes were made was to disguise the sham nature of these presentations, and everyone (TEVA sales representatives, paid speakers and attendees alike), understood the sham nature of these programs. Nevertheless, speakers were paid a significant "honorarium" to present these redundant programs, averaging between \$2,000 and \$2,500 per program.

108. TEVA's network of illicit speaker programs is widespread and involves healthcare professionals throughout the country. TEVA's paid "speakers" include, but are not limited to, the following individuals:

- Dr. B.P.A. (Johnstown, Pennsylvania)
- Dr. N.A. (Detroit, Michigan)
- Dr. M.A. (Oakland, California)
- Dr. S.A. (St. Louis, Missouri)
- Dr. X.B. (Indianapolis, Indiana)
- Dr. L.B. (Anderson, Indiana)
- Dr. P.C. (St. Louis, Missouri)
- Dr. R.D. (Dallas, Texas)
- Dr. L.E. (Toledo, Ohio)
- Dr. M.E. (South Bend, Indiana)
- Ms. M.K.F. (Chesterfield, Missouri)
- Dr. S.G. (South Bend, Indiana)
- Dr. B.G. (Chesterfield, Missouri)
- Dr. L.G. (Herrin, Illinois)
- Dr. M.N.H. (Hartford, Connecticut)
- Dr. O.K. (Detroit, Michigan)
- Dr. T.P.L. (Philadelphia, Pennsylvania)
- Dr. D.M. (Indianapolis, Indiana)
- Dr. R.M. (Lone Tree, Colorado)
- Dr. B.P. (St. Louis, Missouri)
- Dr. K.P. (Richmond, Indiana)
- Dr. B.S. (St. Louis, Missouri)
- Mr. B.S., N.P. (Richmond, Indiana)
- Dr. F.P.T. (St. Louis, Missouri)
- Dr. M.J.T. (St. Louis, Missouri)
- Dr. P.T.R. (South Bend, Indiana)
- Dr. D.R.W. (Northbrook, Illinois)
- Dr. S.Z. (Palo Alto/San Francisco, California)
- Dr. D.D.Z. (South Bend, Indiana)

- Dr. H.Z. (Coral Gables, Florida)<sup>7</sup>
- approximately 500,000 PD patients. Yet, TEVA has devoted hundreds of sales representatives to reach the physicians serving this small patient population, given the lucrative nature of the market. Specifically, TEVA Neuroscience has approximately 200 sales representatives who are spread over three sales areas (*i.e.*, West, Central, and East), 112 territories within these areas, and 22 regions. TEVA's sales representatives "call" on approximately 50 to 80 healthcare providers per territory and each representative will average approximately five "calls" a day.
- sales of the Covered Drugs by paying speakers and, as a consequence, the total number of speaker programs for the Covered Drugs shot up from approximately 1,329 in 2011 to approximately 5,036 in 2012, with approximately 4,600 programs having been completed or scheduled as of August 2013. When compared against the number of MS and PD patients in the U.S., the number of TEVA speaker programs devoted to the Covered Drugs is, in a word, obscene. In recognition of the lack of educational value associated with the paid speaker programs, Plaintiff-Relator Arnstein was recently told by his supervisor that patient programs were of little or no value unless the patient is specifically connected to a paid physician speaker since these are the physicians that TEVA knows will write prescriptions for the Covered Drugs indeed, that is the entire reason that they are paid to be speakers.
- 111. California, New York and Pennsylvania are among the top States for speaker programs. Between 2006 and 2010, for instance, the Southern California/Inland Empire Region was recognized by TEVA as the "Region of the Year" for the highest Copaxone® prescriptions

<sup>&</sup>lt;sup>7</sup> Plaintiffs-Relators provide the initials of each physician and stand ready to provide the full names of each physician if the Court so requires.

for five consecutive years. Among its sales representatives were four-time winners of TEVA's "President's Club" award, which goes to the sales representatives who are in the top ten percent of sales in the Company. Speaker programs were key to obtaining and maintaining these regions' (and their sales representatives') high prescription levels. The same is true for the Philadelphia, Pennsylvania region, which also has four-time "President's Club" awardees who are well-known for conducting plainly excessive numbers of speaker programs, which could not have any educational purpose or value in light of the relatively small number of patients and practitioners in the area, but which undoubtedly is the key to their consistently high sales.

- 112. TEVA aggressively and unabashedly promoted the speaker programs as a way for physicians to make money in exchange for increased Copaxone® and Azilect® prescriptions. For example, up until 2011, as described above, honorarium checks were presented to physicians in green envelopes, conveying the tacit message to physicians that the more scripts they wrote, the more money they made.
- 113. TEVA conveyed its pay-to-play message to high and low prescribers alike. For those physicians whose Copaxone® and Azilect® prescriptions were too low, TEVA refused to give them any additional speaker programs, required them to undergo "training" in order to be added back onto the speakers' list, and insisted that they write more prescriptions if they were to be included on the speakers' list for the following year. As TEVA's management expressly directed, only those physicians who wrote more prescriptions would be allowed to participate in the speaker programs.
- 114. And pay-to-play is exactly what TEVA did (and does). In the case of TEVA's most prized speaker and consultant, Dr. O.K. of Detroit, Michigan, TEVA conducts approximately 80 speaker programs each year with Dr. O.K. It should be noted that it appears as

though TEVA has concealed Dr. O.K.'s payments, as the AHM website has removed his name and totals from the site along with other top speakers. TEVA pays Dr. O.K. a \$2,700 honorarium per program, netting him approximately \$216,000 in honorariums per year. He also is paid by TEVA for performing research and consulting, as well as sitting on various advisory boards. Payments to Dr. O.K. are made to a limited liability corporation created by Dr. O.K. for the express purpose of avoiding public disclosure of the payments. TEVA's return from these kickbacks to Dr. O.K. is astounding – as of April 2013, approximately 80% of the 5,000 patients at Dr. O.K.'s clinic are Copaxone® patients – which means that Dr. O.K. writes approximately \$200 million in Copaxone® prescriptions per year.

\$1,043,576.00 (340 claims) and \$1,478,306.23 (409 claims), respectively, as a result of false claims submitted in connection with Copaxone prescriptions written by Dr. O.K personally. Likewise, the following practitioners identified above also personally wrote prescriptions for the Covered Drugs resulting in false claims for which Medicare Part D provided reimbursement in 2010 and 2011, respectively, in the following amounts: (a) Dr. M.A. (Oakland, CA)(Azilect) -- \$63,025.11 (167 claims) and \$122,415.73 (290 claims); (b) Dr. X.B. (Indianapolis, IN)(Azilect) -- \$30,212.39 (70 claims) and \$31,564.37 (67 claims); (c) Dr. P.C. (St. Louis, MO)(Azilect) -- \$11,099.85 (36 claims) and \$7,882.59 (22 claims); (d) Dr. R.D. (Dallas, TX)(Azilect) -- \$107,142.48 (225 claims) and \$148,170.40 (262 claims); (e) Dr. L.E. (Toledo, OH)(Azilect) -- \$99,711.29 (210 claims) and \$206,596.23 (344 claims); (f) Dr. B.G. (Chesterfield, MO)(Copaxone) -- \$538,284.97 (166 claims) and \$877,513.38 (232 claims); (g) Dr. T.P.L. (Philadelphia, PA)(Copaxone) -- \$969,950.56 (264 claims) and \$1,036,428.93 (242 claims); (h) Dr. D.M. (Indianapolis, IN)(Copaxone) -- \$639,580.46 (211 claims) and \$903,503.33 (247

claims); (i) Dr. R.M. (Lone Tree, CO)(Copaxone) -- \$54,652.30 (18 claims) and \$162,315.39 (45 claims); (j) Dr. B.P. (St. Louis, MO)(Copaxone) -- \$319,662.00 (102 claims) and \$458,887.47 (128 claims); (k) Dr. B.S. (St. Louis, MO)(Copaxone) -- \$497,314.95 (156 claims) and \$787,042.30 (202 claims); (l) Dr. P.T.R. (South Bend, IN)(Copaxone) -- \$216,245.32 (67 claims) and \$300,564.68 (84 claims); (m) Dr. D.R.W. (Northbrook, IL)(Copaxone) -- \$1,072,925.17 (334 claims) and \$1,221,730.26 (319 claims); and (n) Dr. S.Z. (Palo Alto/San Francisco, CA)(Copaxone) -- \$70,345.10 (23 claims) and \$125,938.28 (35 claims).

116. Several examples illustrating the egregious nature of TEVA's speaker programs are detailed below.

## 1. Specific Examples Of Sham Peer-To-Peer Programs

- a. Rotating Journal Club Involving The Same Physician Group And No Outside Attendees
- 117. Between 2007 and 2008, TEVA hosted approximately seven to eight journal clubs with a neurology group consisting of four physicians in South Bend, Indiana, including Dr. S.G., Dr. M.E., Dr. D.D.Z., and Dr. P.T.R. No one other than the physicians in this group was invited to participate in the journal club. The physicians took turns leading a 15-minute discussion of a medical article each month, with the only other attendees being TEVA sales representatives and the non-presenting physicians in the group. Examples of the articles discussed during the meetings include: (1) "A multiparametric MRI study of frontal lobe dementia in multiple sclerosis" (Comi, G., *et al.*); (2) "Interferon β-1b and glatiramer acetate effects on permanent black hole evolution" (Filippi, M., *et al.*); (3) "Twenty-four-month comparison of immunomodulatory treatments a retrospective open label study in 308 RRMS patients treated with beta interferons or glatiramer acetate (Copaxone®)" (Haas, J., *et al.*); (4) "Measurement error of two different techniques for brain atrophy assessment in multiple sclerosis" (Sormani,

M.P., *et al.*); and (5) "A prospective open-label study of glatiramer acetate: over a decade of continuous use in multiple sclerosis patients" (Ford, C.C., Johnson, K.P., *et al.*) (also referred to herein as the "Ford study"). All articles were suggested, chosen, and provided by TEVA. The Ford study, which discussed the effects of Copaxone® on disability, was an off-label article. Despite the short length of the discussions led by the physicians, TEVA paid each presenting physician an honorarium of \$1,500 per discussion. The primary purpose for this journal club was not educational, because all of the information presented was well known to everyone in attendance; it was to drive Copaxone® prescriptions by paying these physicians and, thereby, positively position Copaxone® against the competition through kickbacks.

# b. Speaker Program With No "Peer" Attendees And No Educational Materials Presented

- and Dr. X.B. The program was held at Dunaway's Palazzo Ossigeno, a restaurant in Indianapolis, Indiana. Besides the two speakers, only a TEVA sales representative and a TEVA Regional Sales Manager attended. The topic of this program was, "Dopamine Management in Early to Moderate-to-Advanced Parkinson's Disease: A Case Study Approach." No formal presentation was made, no new material was discussed, and the group only engaged in "small talk" during dinner. Dr. K.P. and Dr. X.B. were each paid an honorarium of \$2,000 for this "program."
- 119. On November 18, 2009, Dr. K.P. spoke at another Azilect® speaker program held at Sullivan's Steakhouse in Indianapolis, Indiana. The topic was the same as the February 18, 2009 program, no formal slides or materials were presented and, once again, no one attended except a TEVA sales representative. Dr. K.P. was paid an honorarium of \$2,000.

- 120. On July 6, 2010, Dr. N.A. was commissioned by TEVA to speak at an Azilect® dinner program held at the Quarry restaurant in Kokomo, Indiana, the topic of which was "A Case Study Approach: Treatment in Early and Moderate-to-Advanced Parkinson's Disease." No slides were presented and the only other participant at the program was a TEVA sales representative. Notwithstanding the lack of any presentation, Dr. N.A. was paid a \$2,000 honorarium.
- 121. On September 20, 2011, TEVA hosted an Azilect® program with Dr. X.B., now of Augusta, Maine, and a top Azilect® prescriber. The program took place at Mitchell's Fish Market Seafood Restaurant & Bar in Carmel, Indiana, and the topic was "The Continuum of Parkinson's Disease Treatment: Enhancing Patient Care: Initial Treatment of Early PD." There were no attendees at the program and no formal slides or materials were presented by Dr. X.B., vet he was paid an honorarium of \$2,000.
- 122. On June 11, 2012, TEVA paid Dr. M.N.H. of Hartford, Connecticut, a high-volume Azilect® speaker and prescriber, to speak at a program held at Charbono's restaurant in Avon, Indiana. The topic was, "The Continuum of Parkinson's Disease Treatment: Enhancing Patient Care: Initial Treatment of Early PD" and, like Dr. X.B.'s September 20, 2011 program, no slides or materials were presented and there were no attendees except TEVA representatives. Despite Dr. M.N.H.'s failure to present formal slides or materials, he was still paid an honorarium of \$2,500.
- 123. More recently, on August 6, 2013, a TEVA speaker dinner program was held at Edge Wild Winery in Chesterfield, Missouri. The speaker program immediately followed a meeting of the St. Louis Region and the sole purpose for having the program was to create a venue for Dr. B.S. to speak. Dr. B.S. is the Director of an MS Clinic in St. Louis, Missouri and a

high-volume prescriber of Copaxone®. Only TEVA representatives attended the speaker program and no outside doctors were invited. Dr. B.S. did not give any formal presentation and only took questions for approximately 25 minutes. Unsurprisingly, Dr. B.S.'s question and answer session provided no new information to the sales representatives in attendance and had no educational value. For this "program," Dr. B.S. was paid an honorarium of \$2,500.

## c. Speaker-To-Speaker Program With No Educational Purpose

- 124. On April 24, 2013, TEVA hosted a Copaxone® speaker program with Dr. O.K. at Patachou on the Park restaurant in Indianapolis, Indiana. As noted above, Dr. O.K. is among TEVA's highest volume speakers for Copaxone®. The only attendees were Dr. D.M., who is also a Copaxone® national speaker, and a TEVA sales representative. Dr. O.K. presented no formal slides or materials during the meeting and relegated his discussion to four cases from the *New England Journal of Medicine* involving progressive multifocal leukoencephalopathy ("PML"), a life-threatening disease associated with Biogen's new oral agent, Tecfidera, none of which is relevant to Copaxone®. Dr. O.K. received a \$2,700 honorarium for this program. The purpose of the program was not educational; rather, Dr. O.K. sought to encourage Dr. D.M. to maintain his Copaxone® prescriptions and slow down his Tecfidera prescriptions, while creating yet another opportunity to pay Dr. O.K.
- 125. The previous year, on January 5, 2012, a similar speaker-to-speaker program with Drs. O.K. and D.M. took place, again with no formal slides or materials presented and with the doctors merely engaging in "small talk." For this program, Dr. O.K. received an honorarium of \$2,500.

- d. Multiple Speaker Programs Over Two Days, With The Same Speaker, Few Attendees, And Minimal Educational Benefit
- 126. In May 2013, TEVA hosted five back-to-back Copaxone® speaker programs over two days with the same speaker, Dr. R.M. Dr. R.M. has a very large MS practice in Colorado and is a leading prescriber and speaker for Copaxone®. For doctors like Dr. R.M., who are high-decile and high-volume script writers, TEVA targets them for back-to-back programs in order to maximize opportunities to pay these doctors and obtain more scripts from them.
- May 14, 2013 at 12:00 p.m. at a private neurology practice in Indianapolis, Indiana. Besides the TEVA sales representatives, only two physicians from within the practice attended and Dr. R.M. presented generalized slides on the topic, "Navigating Options in RRMS." The presentation lasted only 15 minutes and had no educational value or purpose. The two physicians in attendance have approximately 15 to 20 years' experience in neurology between them. As a result, presenting generalized slides about MS and Copaxone® that lacked new content was clearly of no value to these doctors. This program was simply another way for TEVA to pay Dr. R.M.
- 128. Later in the day, at 6:30 p.m., Dr. R.M. spoke at a sparsely attended patient program held at the Indianapolis Marriott North in Indianapolis, Indiana. Approximately ten patients attended and Dr. R.M.'s presentation lasted approximately 15 to 20 minutes. Dr. R.M. again presented generalized slides, this time on the topic, "The Current RRMS Landscape and Available Therapies." He also discussed Copaxone®'s impending new formulation. As a general matter, most patients who attend programs like this one are MS patients who are already on and, thus, familiar with Copaxone®. Therefore, as above, showing them generalized slides about MS and Copaxone® would be of no value to any of them. The true purpose of these

programs, as it was for this patient program with Dr. R.M., was to maintain those patients in attendance on Copaxone® (by providing them with a free meal), while gaining more scripts from Dr. R.M. by paying him to speak.

- 129. The next day, on May 15, 2013 at 12:00 p.m., Dr. R.M. spoke one-on-one with another physician, Dr. K.H., at her office. The topic for this program was "Navigating Options in RRMS." Notably, just six weeks earlier, Dr. K.H. was visited by Dr. D.M., who was paid to speak with Dr. K.H. on the very same topic, of which, to put it mildly, Dr. K.H. was already very familiar since approximately 50% of her MS patients are on Copaxone®. Therefore, there was no value in making this presentation to her. Tellingly, Dr. R.M. did not use any slides or materials for this program and they only discussed the new Copaxone® formulation, as well as general matters about private and solo practice in neurology.
- 130. At 6:30 p.m. on the same day, TEVA hosted another speaker program with Dr. R.M. at Morton's of Chicago restaurant in Indianapolis, Indiana. Once again, the topic was "Navigating Options in RRMS." No doctors attended, and only the paid speaker and TEVA sales representatives were present. Although two doctors originally indicated that they would attend the program, Dr. R.M. would have presented the same generalized slides on MS and Copaxone® to them, none of which would have benefitted these doctors since both know Copaxone® very well, having market shares for Copaxone® of 50% and 71%, respectively. In addition, one of the doctors was previously a Copaxone® speaker. Ultimately, no slides or materials were presented by Dr. R.M. and the total restaurant bill was \$833.00. As per new Company policy, the program was deemed "cancelled" because there was not at least one outside attendee, but Dr. R.M. was still paid because the "cancellation" did not occur within 24 hours.

- Only physicians from within the practice attended, but no outside physicians came. Dr. R.M. did not present any slides or materials; he simply talked generally about changes in medical practices as a result of the PPACA and mentioned Copaxone®'s new formulation. Given the composition of the physicians who attended, the lack of substantive discussion was not surprising among the six doctors, four had market shares of 81%, 50%, 34%, and 16%, respectively, for Copaxone® scripts among their MS patients and, thus, were very familiar with Copaxone®. The purpose for the program was to encourage the physicians to keep their patients on Copaxone® until the new formulation is launched, while providing another opportunity to pay Dr. R.M. and encourage him to keep writing more Copaxone® scripts.
- 132. For all five programs, Dr. R.M. was paid a total honorarium of \$12,500, plus travel and meals. None of the programs had a legitimate purpose. Rather, the honorarium, in full, amounted to pure kickback payments to Dr. R.M.
  - e. Recurring Speaker Programs With The Same Physician, The Same And/Or Few Attendees, And The Same Program Topic
- TEVA hosted a journal club for Copaxone® with Dr. P.T.R. of South Bend, Indiana. The only other person in attendance was Dr. P.T.R.'s nurse practitioner. Dr. P.T.R. was paid an honorarium of \$2,000. Thereafter, TEVA hosted additional speaker programs with Dr. P.T.R. on March 22, 2013, April 19, 2013, and May 3, 2013 at the same venue, each involving the same topic (*i.e.*, "Navigating Options in RRMS"). Nothing new was presented at these programs. Once again, the only person who attended the April 19 and May 3 programs was Dr. P.T.R.'s nurse practitioner. For the March 22 program, in addition to Dr. P.T.R.'s nurse practitioner, Dr. M.E. also attended, but he is also from the same office as Dr. P.T.R. and is a past-paid TEVA

speaker on the same material himself. Dr. P.T.R. was paid an honorarium of \$2,000 for each of these programs as well.

- 134. Although invitations to these programs were sent out, TEVA had no bona fide belief that any invitees would actually attend and sent out invitations only to avoid any compliance issues and create an appearance of propriety. Indeed, TEVA knew that doctors would rarely leave their offices to attend an off-site speaker program unless paid to do so. Nevertheless, TEVA fully intended to continue the speaker programs with Dr. P.T.R. for the remainder of this year, even if no one attended, because she was a key script writer for Copaxone® who wanted to start her own MS clinic soon and was considered by TEVA to be a "rising star" of the region.
- 135. Similarly, on January 8, 2013, February 21, 2013, and May 9, 2013, TEVA paid Dr. B.P.A. of Johnstown, Pennsylvania, to speak at three programs. The programs involved the same topic, "Navigating Options in RRMS," and there was only one attendee for all three programs.

# f. Back-To-Back Speaker Programs Conducted By The Same Speaker(s) On The Same Day

136. On April 8, 2013, TEVA conducted three Azilect® programs with Dr. P.C. of St. Louis, Missouri, one at 7:00 a.m. at Dr. L.G.'s office in Herrin, Illinois, another at 10:00 a.m. at Dr. F.A.'s office in Carbondale, Illinois, and the last one at 11:30 a.m. at a neurological institute in Carbondale, Illinois. Notably, the topic of the first program was "Azilect® as Add-on Therapy in Parkinson's Disease," and the only attendee was Dr. L.G., who is a trained speaker for the Covered Drugs. As such, there was no educational value in Dr. P.C. speaking to Dr. L.G. about the same Azilect® presentation slides and content that she had already been trained on and presented herself. The only purpose for this program was to provide an opportunity to pay Dr.

P.C. to write more Azilect® scripts. The next two programs involved case presentations, which simply discuss a prototypical patient candidate for the drug. Dr. P.C. was paid an honorarium of \$7,500 total for all three programs.

- 137. Similarly, on February 8, 2013, TEVA paid Dr. S.A. and Dr. B.P. of St. Louis, Missouri, to conduct speaker programs for the Covered Drugs at the same doctor's offices at the same time. The first set of programs took place at 8:00 a.m. at Dr. C.K.'s office in Murray, Kentucky and the second set took place at 12:30 p.m. at Dr. H's office in Paducah, Kentucky, with Dr. S.A. conducting the Azilect® program and Dr. B.P. conducting the Copaxone® program. The topic for both Copaxone® programs was "Navigating Options in RRMS," and the topics for the Azilect® programs were "Managing Parkinson's Disease: The Role of Azilect®" and "Azilect® as Add-on Therapy in Parkinson's Disease." Only two doctors in total attended the programs and no information of educational value was presented, yet Drs. S.A. and B.P. were paid a total honorarium of \$10,000 for all of the programs.
- 138. In yet another example, Dr. D.R.W. of Northbrook, Illinois, who is a high-volume script writer for Copaxone®, was paid by TEVA to speak at three back-to-back Copaxone® programs on January 31, 2013, all of which involved the same topic, "Navigating Options in RRMS," and had a total of one attendee. The programs took place at 12:00 p.m. at the Sterling/Rock Falls Clinic in Sterling, Illinois, at 3:30 p.m. at Innkeeper's Fresh Roast Coffee in Galesburg, Illinois, and at 6:00 p.m. at the Bix Bistro restaurant in Davenport, Iowa. Dr. D.R.W. was paid a total honorarium of \$7,500 for all three programs.
- 139. It is well-known among TEVA representatives that Dr. D.R.W., who is an important MS specialist in the Chicago region, like other paid speakers, will write more prescriptions if he is paid to do so. Consequently, having multiple, consecutive programs within

as short a timeframe as possible was an easy way for TEVA to make these payments to Dr. R.W., as it did with other physicians all over the country, in exchange for increased TEVA prescriptions.

- 140. True to form, approximately ten weeks later, on April 15, 2013, TEVA paid Dr. R.W. for back-to-back programs in California. The first program took place at 12:00 p.m. at a doctor's office in Santa Monica, California and had two attendees. The second program took place at 6:30 p.m. at Jer-Ne Restaurant & Bar in Marina Del Rey, California and had no attendees. As before, the topic for both programs was the same "Navigating Options in RRMS" which program provides no new information to physicians in the field. Dr. R.W. was paid a total honorarium of \$5,000 for these two programs.
- 141. On May 8, 2013, Dr. T.P.L., who is another top speaker for TEVA, was paid by TEVA to speak at three consecutive Copaxone® programs that discussed the same topic, "Navigating Options in RRMS," and did not have a single attendee. The programs took place at 9:00 a.m. at a neurologic institute in Amherst, New York, at 12:00 p.m. at another neurologic center in Williamsville, New York, and at 6:00 p.m. at Tempo Restaurant in Buffalo, New York. Dr. T.P.L. was paid \$2,500 for each program, for a total honorarium of \$7,500.

## g. Rotating Speakers and Attendees

As part of TEVA's scheme to disguise the true nature of its physician speaker programs, TEVA regularly had physician-speakers serve as attendees at speaking events of other physican-speakers to provide a veneer of legitimacy to these events and regularly had speakers and speaker-attendees rotate – with one serving as speaker and the other as attendee – and then having the two switch roles – so that both physicians could be compensated and even though no

substantive or new material was discussed by the two physicians who already were well versed in the subject matter.

## 2. Specific Examples Of Sham Patient Programs

- a. Patient Programs With No "Patient" Attendees
- Copaxone® advocate for TEVA, presented a Copaxone® program at the Olde Richmond Inn in Richmond, Indiana. In addition to an expensive meal at the nicest restaurant in Richmond, Mr. B.S. also received a \$2,000 honorarium, despite the fact that he failed to discuss or present any educational materials concerning Copaxone®. The event was not attended by a single prospective Copaxone® patient those in attendance solely consisted of Mr. B.S., the Copaxone® Patient Advocate (an area patient on Copaxone who is paid and otherwise rewarded by TEVA for advocating the use of Copaxone to other patients and who, by virtue of his or her role, already is knowledgeable and conversant regarding all of Copaxone's approved uses and therapeutic benefits) and her husband, and a TEVA sales representative. The sole purpose for this program was simple as a nurse practitioner, Mr. B.S. is able to write prescriptions and, as such, the program was an opportunity to pay Mr. B.S. to encourage him to write Copaxone® scripts. By the same token, by influencing her staff with significant cash payments, Dr. K.P. was also encouraged to continue her Copaxone® prescriptions at a high level.
- 144. On June 25, 2013, TEVA paid Dr. L.B. to present at a Copaxone® program over lunch at a Ruby Tuesday's restaurant in Anderson, Indiana. The sole purpose of the program was to induce Dr. L.B., who is a board certified neurologist with a high market share for current Copaxone® scripts, to continue to write Copaxone® prescriptions by lining his pockets with sham honorariums. TEVA paid Dr. L.B. \$1,500, despite the fact that the attendees at this

program were limited to Dr. L.B., the Copaxone® Patient Advocate, and a TEVA sales representative. Dr. L.B. failed to present any materials and/or slides concerning Copaxone®.

## b. Patient Program Honorariums For Multiple Speakers From The Same Medical Practice

145. In keeping with TEVA's tactic of paying multiple speakers from the same medical practice to present at patient programs throughout the country, on January 29, 2013, TEVA paid both Dr. B.J.G., and her nurse practitioner, Ms. M.K.F., to present a Copaxone® program on the same topic, "The Current RRMS Landscape and Available Therapies." This program was held at the Marriot West in St. Louis, Missouri. In addition, on February 20, 2013 and March 12, 2013, TEVA paid Dr. B.J.G. and Ms. M.K.F. for programs held at an MS center where Dr. B.J.G. serves as the Director. Once again, Dr. B.J.G. and Ms. M.K.F. presented on exactly the same topic, "The Current RRMS Landscape and Available Therapies." For each of these programs, Dr. B.J.G. and Ms. M.K.F. received \$2,500 and \$2,000, respectively, in honorarium payments from TEVA. Thus, in a six-week period, Dr. B.J.G. was paid \$7,500 and Ms. M.K.F. was paid \$6,000 to present at the same exact patient program. As this example illustrates, TEVA's patient programs typically consisted of the same material and presentation being completed time and time again and, as such, there can be no legitimate reason to pay both healthcare providers from the same practice other than to continue to effectively influence their Copaxone® scripts. In the case of the duel payments to Dr. B.J.G. and Ms. M.K.F., TEVA's objective has been successful to date; indeed, Dr. B.J.G. does not allow any Copaxone® competitor representatives into her MS center.

## c. Back-To-Back Speaking Engagements

146. In an effort to increase the amount of honorarium a healthcare provider may receive, it is common for TEVA sales representatives to schedule peer-to-peer speaking

engagements on the same day as a patient program. For example, on February 11, 2013, TEVA paid nurse practitioner, Ms. M.K.F., for two separate speaking engagements within an hour of each other. The first event, scheduled for 5:30 p.m. at Addison's Restaurant in Columbia, Missouri, was a peer-to-peer program designed for nurse education, although no one attended the program. Despite the lack of attendance and Ms. M.K.F.'s failure to present, TEVA still paid her a \$2,000 honorarium. An hour later, at 6:30 p.m., TEVA hosted Ms. M.K.F. for a Copaxone® patient program at the University of Missouri. As a result, Ms. M.K.F. was paid an additional \$2,000 honorarium, plus her out-of-pocket expenses. As the nurse practitioner for one of TEVA's top Copaxone® prescribing doctors, these back-to-back programs by Ms. M.K.F. were simply another method for TEVA to encourage – and pay for – more Copaxone® prescriptions from Dr. B.J.G.'s office.

## d. The Same Patient Events With The Same Speaker And Same Attendees

- 147. On a recurring basis, TEVA's sales representatives throughout the country routinely schedule the same patient programs with the same speakers, at the same location, and which, in turn, often draw the same exact attendees. For example, on May 15, 2013, May 28, 2013, July 10, 2013, September 18, 2013, and November 6, 2013, Dr. F.P.T., a professor of neurology, was paid by TEVA to conduct the very same program at Maggiano's, "The Current RRMS Landscape and Available Therapies," yielding him a \$2,500 honorarium for each program. On April 16, 2013, just one month before the May 15, 2013 program, TEVA paid Dr. M.J.T., an assistant professor of neurology, to speak at the very same program at Maggiano's, for which he was paid another \$2,500 honorarium.
- 148. Importantly, and as mentioned earlier, an MS diagnosis, which, according to the National Institute of Neurological Disorders and Stroke, impacts approximately 250,000 to

300,000 people in the U.S., simply does not justify the volume and frequency of these types of patient programs. As a result of their ongoing nature, these programs typically attract the same patients and their family members, who are already familiar with Copaxone® and whose purpose for attending is not educational, and who will often leave once dinner is done but prior to the completion of the program.

## e. Elimination From Speakers' Bureau Due To Low Prescriptions

- 149. As discussed above, TEVA not only rewarded those physicians who played the game and kept up their Covered Drugs prescriptions through honorarium payments, the Company penalized those whose prescriptions were deemed to be too low by refusing to give them any speaker programs. This happened to Dr. N.A., a neurology and epilepsy specialist from Michigan. Dr. N.A. last presented at an Azilect® program on July 6, 2010, for which he was paid a \$2,000 honorarium, even though there were no attendees and no formal slides or materials presented. After this program, however, TEVA removed Dr. N.A. from the speakers' bureau because there was no increase in his Azilect® prescriptions.
- 150. Such was also the case with Dr. C.H., who, in or around fall of 2012, was also removed from the speakers' bureau by TEVA due to insufficient Copaxone® prescriptions.

  TEVA advised Dr. C.H. that he would not be given any further speaking opportunities until he increased his Copaxone® prescriptions. After removing him from the speakers' bureau due to low scripts, Dr. C.H. was allowed back on the basis that there was an opening. In his first month of being back on the speakers' bureau, Dr. C.H. revealed that he had received the message -- he wrote four new Copaxone® prescriptions and continues to do speaker programs.

- B. TEVA's "Silver Bullet" For Increasing Copaxone® And Azilect® Prescriptions
- 151. TEVA's illegal kickback scheme was and continues to be devised and carried out by TEVA at the highest levels of the Company.
- 152. In January 2008, Plaintiffs-Relators' manager confirmed TEVA's long-standing policy that advocate "development" was the means by which the Covered Drugs would be marketed and sold. TEVA's management directed its sales force to use speaker programs to incentivize physicians to write more prescriptions for the Covered Drugs, stating: "We have committed as a group to try to use as many of the AHM programs as possible and develop our regional advocates for outside programs." (Emphasis added.)
- Professional Leadership Team Meeting in Westminster, Colorado, telling the entire leadership team consisting of directors, managers and management designated candidates: "AHMs, AHMs this is the closest thing I have to a silver bullet." (Emphasis added.)

  Management further emphasized: "Invest wisely who are your advocates? Who do you want to be your advocates? Develop educational opportunities that align with your goals Journal Clubs, patient programs, etc." Indeed, the "Best Practices: Regional Approaches Seminar" was designed and devoted to instructing the leadership team on how to achieve greater prescriptions through speaker programs and how the sales force would be financially rewarded through so-called "Advocate Development" and "Market Share Change" contests. The overarching message to TEVA's leadership team was the more speaking opportunities you create to pay doctors, the more prescriptions they will write for TEVA, and the more financial rewards you will receive.
- 154. The message to increase the number of speaker programs did not stop there.

  TEVA's management consistently reinforced the message to the sales force in emails urging

them to set up and complete as many speaker programs as possible (*e.g.*, "I would like to see us [the] #1 region in regards to using our programs"), as well as in charts and graphs circulated to the sales force setting out the number of speaker programs by region and sales representative, and through threats that if the sales representatives did not generate more speaker programs, they would lose them. At all relevant times, TEVA's top priority has been the *quantity* of speaker programs, not the quality, and it evaluated and rewarded the sales force based on the number of speaker programs they placed and completed.

155. To date, TEVA continues to pay physicians for presenting the same speaker program over and over again. Indeed, TEVA has not provided the sales force with any new materials to present at the programs in a number of years. Nevertheless, TEVA continues to impress upon the sales force to set up more and more of these programs in order to drive the market share for the Covered Drugs. This message was reiterated at TEVA's Central Area Sales Meeting in October 2013, where TEVA lauded those sales representatives who completed the most speaker programs and emphasized the direct correlation between increased speaker programs and attaining TEVA's sales goals. In other words, pay doctors to speak and they will write more prescriptions for the Covered Drugs. Against this background, it is hardly surprising that TEVA's paid speakers account for 80% of all Azilect® prescriptions written to date.

# VI. TEVA Conducted Fraudulent Speaker Programs <u>With Respect To The Covered Drugs</u>

- 156. As discussed above, TEVA conducted fraudulent speaker programs with respect to the Covered Drugs.
- 157. TEVA carefully tracked the return-on-investment ("ROI") associated with its speaker programs by ensuring that TEVA's paid speakers continued to write and increased their prescriptions of the Covered Drugs.

158. Furthermore, the fact that doctors were paid in connection with TEVA's speaker programs influenced their prescription writing with respect to the Covered Drugs.

## VII. TEVA Caused Thousands Of False Claims To Be Submitted To And Paid For By Federal Health Care Programs

- 159. TEVA caused many thousands of prescriptions to be written as a result of payments and/or other remuneration made in connection with speaker programs that were kickbacks to doctors. TEVA paid tens of millions of dollars in kickbacks to physicians in the form of honoraria and/or other remuneration in connection with speaker programs concerning the Covered Drugs between 2006 and to date. On average each of these doctors wrote many hundreds of thousands of dollars' worth of prescriptions for the Covered Drugs that were paid for by the Government Healthcare Programs.
- 160. Exhibit "A" contains a representative sample of false claims tainted by kickbacks for which reimbursement was obtained from the Medicare Part D program in 2010 and 2011. As detailed in Exhibit "A," based upon this sample of false claims alone, the Medicare Part D program paid over \$63 million dollars in claims that were tainted by TEVA's paid-speaker scheme in violation of the AKS in 2010 and 2011.
- 161. TEVA is liable to the Government for damages based on the payment of the above claims and all other claims submitted to the Government Healthcare Programs for prescriptions written by these physicians for the Covered Drugs beginning from the time they began receiving honoraria payments or other remuneration and continuing to date, because the claims were the result of prescriptions induced by honoraria or other remuneration.
- 162. Compliance with the AKS is a precondition of payment by virtue of federal and state statutes, regulations, provider agreements, and contracts.

- 163. The certifications and attestations signed by physicians, pharmacies, PBMs and Part D sponsors certified compliance with the AKS. Kickbacks that were paid to physicians as alleged herein rendered those certifications and attestations false. Those false statements were material to the false claims submitted for prescriptions written by the doctors that took the kickbacks from TEVA.
- 164. Claims for TEVA's prescriptions drugs arising from the kickbacks expressly and impliedly misrepresent compliance with a material condition of payment, to wit, compliance with the AKS. Claims that include items or services resulting from a violation of the AKS constitute false or fraudulent claims under the AKS. 42 U.S.C. §1320a-7b(b).
- 165. By providing remuneration to physicians and other health care professionals, TEVA intended to induce those physicians to prescribe the Covered Drugs. It was reasonably foreseeable that some of those prescriptions would be for federal health care program beneficiaries and that claims for those prescriptions would be submitted to the Government Healthcare Programs. Thousands of such prescriptions or claims based on such prescriptions were, in fact, submitted to and paid for by the Government Healthcare Programs.
- Healthcare Program coverage policy, was completely undermined by the unlawful marketing of Defendant. The physicians prescribing the Covered Drugs did not necessarily do so because they believed, based on their review of peer-reviewed medical literature, or discussions with their colleagues, that the drugs would help their patients; rather the drugs were often prescribed because the physicians were actively pursued and enticed by TEVA with kickbacks and off-label promotions.

## COUNT I – FCA

- 167. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 168. This is a claim by Plaintiffs-Relators, on behalf of the United States, for treble damages and penalties under the FCA, 31 U.S.C. §§ 3729-3733, against Defendant, for knowingly causing to be presented false claims to Government Healthcare Programs. From 2003 through the present in the Southern District of New York and elsewhere throughout the United States, Defendant has knowingly and willfully violated the FCA by submitting and causing false claims to be submitted.
- 169. Defendant has knowingly caused pharmacies and other healthcare providers to submit claim forms for payment, knowing that such false claims would be submitted to federal and state Government Healthcare Programs for reimbursement, and knowing that such Government Healthcare Programs were unaware that they were reimbursing for prescriptions induced by kickbacks and/or for non-covered uses and, therefore, false claims. By virtue of the acts alleged herein, Defendant knowingly presented, or caused to be presented, false or fraudulent claims to the United States Government for payment or approval, in violation of 31 U.S.C. §3729(a)(1)(A) and 31 U.S.C. §3729(a)(1)(B).
- 170. Defendant has violated 31 U.S.C. § 3729(a)(1)(B) by causing the States to submit false claims to the United States Government on Form CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program), which falsely certified that all drugs for which federal reimbursement was sought, including the Covered Drugs, were paid for in compliance with federal law, including the AKA, yet the States sought reimbursement from the United States Government for all Covered Drugs expenditures.

- 171. Defendant caused false claims to be submitted, resulting in Government Healthcare Program reimbursement to healthcare providers in the millions of dollars, in violation of the FCA, 31 U.S.C. § 3729, *et seq.* and the AKA, 42 U.S.C. § 1320a-7b(b)(2)(A).
- 172. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim presented or caused to be presented.

WHEREFORE, Plaintiffs-Relators respectfully request this Court enter judgment against Defendant as follows:

- (a) That the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims alleged within this Complaint, as the FCA, 31 U.S.C. § 3729, et seq. provides;
- (b) That civil penalties of \$11,000 be imposed for each and every false claim that Defendant caused to be presented to the Government Healthcare Programs under the FCA;
- (c) That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Plaintiffs-Relators necessarily incurred in bringing and prosecuting this case;
- (d) That the Plaintiffs-Relators be awarded the maximum amount allowed pursuant to the FCA; and
- (e) That the Court award such other and further relief as it deems proper.

## COUNT II - CALIFORNIA FALSE CLAIMS ACT

- 173. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 174. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650, *et seq*.
  - 175. Cal. Gov't Code § 12651(a) provides liability for any person who:

- (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof, a false claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
- (3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision; and/or
- (4) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.
- 176. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code § 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code §14107.2.
- 177. Defendant violated Cal. Bus. & Prof. Code § 650 and 650.1 and Cal. Welf. & Inst. Code §14107.2 by engaging in the conduct alleged herein.
- 178. Defendant furthermore violated Cal. Gov't Code § 12651(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of California by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA, Cal. Bus. & Prof. Code § 650-650.1 and Cal. Welf. & Inst. Code § 14107.2 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 179. The State of California, by and through the California Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
  - 180. Compliance with applicable Medicare, Medi-Cal and the various other federal and

state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of California in connection with Defendant's conduct. Compliance with applicable California statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of California.

- 181. Had the State of California known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 182. As a result of Defendant's violations of Cal. Gov't Code § 12651(a), the State of California has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 183. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of themselves and the State of California.
- 184. This Court is requested to accept supplemental jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

#### To the STATE OF CALIFORNIA:

(1) Three times the amount of actual damages which the State of California has sustained as a result of Defendant's conduct;

- (2) A civil penalty of up to \$10,000 for each false claim which Defendant presented or caused to be presented to the State of California;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

#### To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT III - COLORADO MEDICAID FALSE CLAIMS ACT

- 185. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 186. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Colorado to recover treble damages and civil penalties under the Colorado Medicaid False Claims Act, C.R.S.A. § 25.5-4-304, *et seq*.
- 187. Colorado's Medicaid False Claims Act, C.R.S.A. § 25.5-4-304, provides for liability for any person who:
  - (a) Knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
  - (b) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;
  - (c) Has possession, custody, or control of property or money used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and knowingly delivers, or causes to be delivered, less than all of the money or property;

- (d) Authorizes the making or delivery of a document certifying receipt of property used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;
- (e) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state in connection with the "Colorado Medical Assistance Act" who lawfully may not sell or pledge the property;
- (f) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act," or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act"; ... or
- (g) Conspires to commit a violation of paragraphs (a) to (f) of this subsection (1).
- 188. In addition, C.R.S.A. § 25.5-4-414 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made in whole or in part, under the Colorado Medicaid program.
- 189. Defendant violated the Colorado Medicaid False Claims Act by engaging in the conduct alleged herein.
- 190. Defendant further violated the Colorado Medicaid False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Colorado by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA and C.R.S.A. § 25.5-4-414, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
  - 191. The State of Colorado, by and through the Colorado Medicaid program and other

state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

- 192. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Colorado in connection with Defendant's conduct. Compliance with applicable Colorado statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Colorado.
- 193. Had the State of Colorado known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 194. As a result of Defendant's violations of the Colorado Medicaid False Claims Act, the State of Colorado has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 195. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the Colorado Medicaid False Claims Act on behalf of themselves and the State of Colorado.
- 196. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Colorado, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

#### To the STATE OF COLORADO:

- (1) Three times the amount of actual damages which the State of Colorado has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the State of Colorado;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

#### To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to Colorado Medicaid False Claims Act and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## **COUNT IV – CONNECTICUT FALSE CLAIMS ACT**

- 197. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 198. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Connecticut to recover treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301a, *et seq*.
  - 199. Conn. Gen. Stat. § 17b-301b imposes liability as follows:
    - (a) No person shall:
      - (1) Knowingly present, or cause to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval under a medical assistance program administered by the Department of Social Services;

- (2) Knowingly make, use or cause to be made or used, a false record or statement to secure the payment or approval by the state of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services;
- (3) Conspire to defraud the state by securing the allowance or payment of a false or fraudulent claim under a medical assistance program administered by the Department of Social Services;
- (4) Having possession, custody or control of property or money used, or to be used, by the state relative to a medical assistance program administered by the Department of Social Services, and intending to defraud the state or willfully to conceal the property, deliver or cause to be delivered less property than the amount for which the person receives a certificate or receipt;
- (5) Being authorized to make or deliver a document certifying receipt of property used, or to be used, by the state relative to a medical assistance program administered by the Department of Social Services and intending to defraud the state, make or deliver such document without completely knowing that the information on the document is true;
- (6) Knowingly buy, or receive as a pledge of an obligation or debt, public property from an officer or employee of the state relative to a medical assistance program administered by the Department of Social Services, who lawfully may not sell or pledge the property; or
- (7) Knowingly make, use or cause to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state under a medical assistance program administered by the Department of Social Services.
- 200. In addition, Conn. Gen. Stat. § 53a-161c prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Connecticut Medicaid program.
- 201. Defendant violated the Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301a, *et seq.* by engaging in the conduct alleged herein.

- 202. Defendant further violated the Connecticut False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Connecticut by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA, and Conn. Gen. Stat. § 53a-161c, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 203. The State of Connecticut, by and through the Connecticut Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
- 204. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Connecticut in connection with Defendant's conduct. Compliance with applicable Connecticut statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Connecticut.
- 205. Had the State of Connecticut known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 206. As a result of Defendant's violations of the Connecticut False Claims Act, the State of Connecticut has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

- 207. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the Connecticut False Claims Act on behalf of themselves and the State of Connecticut.
- 208. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Connecticut, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

#### To the STATE OF CONNECTICUT:

- (1) Three times the amount of actual damages which the State of Connecticut has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the State of Connecticut;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

## To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301a *et seq.* and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (2) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT V – DELAWARE FALSE CLAIMS AND REPORTING ACT

209. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as

though fully set forth herein.

- 210. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.
  - 211. 6 Del. C. § 1201(a) provides liability for any person who:
    - (1) knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;
    - (2) knowingly makes, uses, or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; and/or
    - (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.
- 212. In addition, 31 Del. C. § 1005 prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebates) directly or indirectly, overtly or covertly, in cash or in kind, in return for the furnishing of any medical care or services for which payment may be made, in whole or in part, under any public assistance program.
  - 213. Defendant violated 31 Del. C. § 1005 by engaging in the conduct alleged herein.
- 214. Defendant further violated 6 Del. C. § 1201(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Delaware by its deliberate and systematic violation of federal and state laws, including the FDCA, the AKA, and 31 Del. C. § 1005 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 215. The State of Delaware, by and through the Delaware Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

- 216. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Delaware in connection with Defendant's conduct. Compliance with applicable Delaware statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Delaware.
- 217. Had the State of Delaware known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 218. As a result of Defendant's violations of 6 Del. C. § 1201(a), the State of Delaware has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 219. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to 6 Del. C. § 1203(b) on behalf of themselves and the State of Delaware.
- 220. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Delaware, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

## To the STATE OF DELAWARE:

(1) Three times the amount of actual damages which the State of Delaware has sustained as a result of Defendant's conduct;

- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which Defendant caused to be presented to the State of Delaware;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

#### To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to 6 Del C. § 1205, and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT VI - FLORIDA FALSE CLAIMS ACT

- 221. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 222. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081, *et seq*.
  - 223. Fla. Stat. § 68.082(2) provides liability for any person who:
    - (a) knowingly presents, or causes to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval;
    - (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency; or
    - (c) conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed-or paid.

- 224. In addition, Fla. Stat. § 409.920 makes it a crime to:
  - (c) knowingly charge, solicit, accept, or receive anything of value, other than an authorized copayment from a Medicaid recipient, from any source in addition to the amount legally payable for an item or service provided to a Medicaid recipient under the Medicaid program or knowingly fail to credit the agency or its fiscal agent for any payment received from a third-party source; or

\* \* \*

- (e) knowingly, solicit, offer, pay or receive any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, or arranging, for or recommending, obtaining, purchasing, leasing, or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.
- 225. Fla. Stat. §456.054(2) also prohibits the offering, payment, solicitation, or receipt of a kickback to a healthcare provider, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for referring or soliciting patients.
- 226. Defendant violated Fla. Stat. § 409.920(c) and (e) and §456.054(2) by engaging in the conduct alleged herein.
- 227. Defendant further violated Fla. Stat. § 68.082(2) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Florida by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA, Fla. Stat. § 409.920(c) and (e) and §456.054(2) and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
  - 228. The State of Florida, by and through the Florida Medicaid program and other state

healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

- 229. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with Defendant's conduct. Compliance with applicable Florida statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Florida.
- 230. Had the State of Florida known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 231. As a result of Defendant's violations of Fla. Stat. § 68.082(2), the State of Florida has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 232. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of themselves and the State of Florida.
- 233. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Florida, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

#### To the STATE OF FLORIDA:

- (1) Three times the amount of actual damages which the State of Florida has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the State of Florida;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

#### To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT VII - GEORGIA FALSE MEDICAID CLAIMS ACT

- 234. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 235. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Georgia to recover treble damages and civil penalties under the Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168, *et seq*.
  - 236. The Georgia False Medicaid Claims Act imposes liability on any person who:
    - (1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
    - (2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;

- (3) Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid;
- (4) Has possession, custody, or control of property or money used or to be used by the Georgia Medicaid program and, intending to defraud the Georgia Medicaid program or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate of receipt;
- (5) Being authorized to make or deliver a document certifying receipt of property used, or to be used, by the Georgia Medicaid program and, intending to defraud the Georgia Medicaid program, makes or delivers the receipt without completely knowing that the information on the receipt is true;
- (6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Georgia Medicaid program who lawfully may not sell or pledge the property; or
- (7) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay, repay, or transmit money or property to the State of Georgia.
- 237. Defendant violated the Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168, *et seq.*, by engaging in the conduct alleged herein.
- 238. Defendant further violated the Georgia False Medicaid Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Georgia by its deliberate and systematic violation of federal and state laws, including the FDCA and the federal AKA, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 239. The State of Georgia, by and through the Georgia Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
  - 240. Compliance with applicable Medicare, Medicaid and the various other federal and

state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Georgia in connection with Defendant's conduct. Compliance with applicable Georgia statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Georgia.

- 241. Had the State of Georgia known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 242. As a result of Defendant's violations of the Georgia False Medicaid Claims Act, the State of Georgia has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 243. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the Georgia False Medicaid Claims Act on behalf of themselves and the State of Georgia.
- 244. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Georgia, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

## To the STATE OF GEORGIA:

- (1) Three times the amount of actual damages which the State of Georgia has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$11,000 for each

- false claim which Defendant caused to be presented to the State of Georgia;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

#### To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168, and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## **COUNT VIII – HAWAII FALSE CLAIMS ACT**

- 245. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 246. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21, *et seq*.
  - 247. Haw. Rev. Stat. § 661-21(a) provides liability for any person who-
    - (1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
    - (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid for by the state;
    - (3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid; and/or

\* \* \*

- (8) is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim.
- 248. Defendant violated Haw. Rev. Stat. §661-21(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Hawaii by its deliberate and systematic violation of federal and state laws, including the FDCA and AKA, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 249. The State of Hawaii, by and through the Hawaii Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
- 250. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Hawaii in connection with Defendant's conduct. Compliance with applicable Hawaii statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Hawaii.
- 251. Had the State of Hawaii known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 252. As a result of Defendant's violations of Haw. Rev. Stat. § 661-21(a), the State of Hawaii has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

- 253. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of themselves and the State of Hawaii.
- 254. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Hawaii, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

## To the STATE OF HAWAII:

- (1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendant's illegal conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the State of Hawaii;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

## To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to Haw. Rev. Stat. §661-27 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT IX – ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

255. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.

- 256. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175, *et seq*.
  - 257. 740 ILCS 175/3(a) provides liability for any person who:
    - (1) knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;
    - (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State; or
    - (3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.
- 258. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Illinois Medicaid program.
- 259. Defendant violated 305 ILCS 5/8A-3(b) by engaging in the conduct alleged herein.
- 260. Defendant furthermore violated 740 ILCS 175/3(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Illinois by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA, and the Illinois Vendor Fraud and Kickback statute, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
  - 261. The State of Illinois, by and through the Illinois Medicaid program and other state

healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

- 262. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Illinois in connection with Defendant's conduct. Compliance with applicable Illinois statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Illinois.
- 263. Had the State of Illinois known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 264. As a result of Defendant's violations of 740 ILCS 175/3(a), the State of Illinois has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 265. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to 740 ILCS 175/3(b) on behalf of themselves and the State of Illinois.
- 266. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Illinois, in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendant:

#### To the STATE OF ILLINOIS:

- (1) Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the State of Illinois;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

# To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to 740 ILCS 175/4(d) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

# COUNT X - INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

- 267. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 268. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Indiana Code 5-11-5.5, *et seq.*, which imposes liability on:
  - (b) A person who knowingly or intentionally:
  - (1) presents a false claim to the state for payment or approval;
  - (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
  - (3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;

- (4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;
- (5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;
- (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;
- (7) conspires with another person to perform an act described in subdivisions (1) through (6); or
- (8) causes or induces another person to perform an act described in subdivisions (1) through (6). . . .
- 269. In addition, Indiana Code § 5-11-5.5, *et seq.*, prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Indiana Medicaid program.
- 270. Defendant violated Indiana's False Claims Act by engaging in the conduct alleged herein.
- 271. Defendant further violated Indiana's False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Indiana by its deliberate and systematic violation of federal and state laws, including the FDCA and federal AKA, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 272. The State of Indiana, by and through the Indiana Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
  - 273. Compliance with applicable Medicare, Medicaid and the various other federal and

state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Indiana in connection with Defendant's conduct. Compliance with applicable Indiana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Indiana.

- 274. Had the State of Indiana known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 275. As a result of Defendant's violations of Indiana's False Claims Act, the State of Indiana has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 276. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Indiana Code § 5-11-5.5, *et seq.*, on behalf of themselves and the State of Indiana.
- 277. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Indiana, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

## To the STATE OF INDIANA:

- (1) Three times the amount of actual damages which the State of Indiana has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the State of Indiana;

- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

## To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to Indiana Code § 5-11-5.5, *et seq.*, and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT XI - IOWA FALSE CLAIMS LAW

- 278. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 279. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Iowa to recover treble damages and civil penalties under the Iowa False Claims Law, I.C.A. § 685.1, *et seq*.
- 280. Iowa False Claims Law, I.C.A. § 685.2, in pertinent part, provides for liability for any person who:
  - (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
  - (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; and/or
  - (c) Conspires to commit a violation of paragraph "a," "b," "d," "e," "f," or "g."
- 281. Defendant violated the Iowa False Claims Law, I.C.A. § 685.1, *et seq.*, by engaging in the conduct described herein.

- 282. Defendant furthermore violated the Iowa False Claims Law, I.C.A. § 685.1, *et seq.*, and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Iowa by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 283. The State of Iowa, by and through the Iowa Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
- 284. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Iowa in connection with Defendant's conduct. Compliance with applicable Iowa statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Iowa.
- 285. Had the State of Iowa known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 286. As a result of Defendant's violations of the Iowa False Claims Law, I.C.A. § 685.1, *et seq.*, the State of Iowa has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 287. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Iowa False Claims

Law, I.C.A. § 685.1, et seq., on behalf of themselves and the State of Iowa.

288. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Iowa, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

## To the STATE OF IOWA:

- (1) Three times the amount of actual damages which the State of Iowa has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which Defendant caused to be presented to the State of Iowa;
- (3) Prejudgment interest; and/or
- (4) All costs incurred in bringing this action.

#### To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to Iowa False Claims Law, I.C.A. § 685.1, *et seq.*, and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT XII – LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

- 289. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
  - 290. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of

Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 437.1, *et seq*.

- 291. La. Rev. Stat. Ann. § 438.3 provides:
  - (A) No person shall knowingly present or cause to be presented a false or fraudulent claim;
  - (B) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds; and
  - (C) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.
- 292. In addition, La. Rev. Stat. Ann. § 438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes and/or rebates, directly or indirectly, overtly or covertly, in cash or in kind, for furnishing healthcare goods or services paid for, in whole or in part, by the Louisiana medical assistance programs.
- 293. Defendant violated La. Rev. Stat. Ann. § 438.2(A) by engaging in the conduct alleged herein.
- 294. Defendant further violated La. Rev. Stat. Ann. §438.3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Louisiana by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA and La. Rev. Stat. Ann. § 438.2(A), and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
  - 295. The State of Louisiana, by and through the Louisiana Medicaid program and other

state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

- 296. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Louisiana in connection with Defendant's conduct. Compliance with applicable Louisiana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Louisiana.
- 297. Had the State of Louisiana known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 298. As a result of Defendant's violations of La. Rev. Stat. Ann. § 438.3, the State of Louisiana has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 299. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to La. Rev. Stat. Ann. §439.1(A) on behalf of themselves and the State of Louisiana.
- 300. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Louisiana, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

#### To the STATE OF LOUISIANA:

- (1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the State of Louisiana;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

## To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

# COUNT XIII - MASSACHUSETTS FALSE CLAIMS ACT

- 301. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 302. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the Commonwealth of Massachusetts for treble damages and penalties under the Massachusetts False Claims Act, Mass. Gen. Laws Ann. Chap. 12 § 5A, *et seq*.
  - 303. Mass. Gen. Laws Ann. Chap. 12 § 5B, provides liability for any person who:
    - (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
    - (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth;

(3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim; or

\* \* \*

- (9) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.
- 304. In addition, Mass. Gen. Laws Ann. Chap. 118E § 41 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any good, service or item for which payment may be made, in whole or in part, under the Massachusetts Medicaid program.
- 305. Defendant violated Mass. Gen. Laws Ann. Chap. 118E § 41 by engaging in the conduct alleged herein.
- 306. Defendant further violated Mass. Gen. Laws Ann. Chap. 12 § 5B and knowingly caused hundreds of thousands of false claims to be made, used and presented to the Commonwealth of Massachusetts by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA, Mass. Gen. Law Ann. Chap. 118E § 41 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 307. The Commonwealth of Massachusetts, by and through the Massachusetts

  Medicaid program and other state healthcare programs, and unaware of Defendant's conduct,

  paid the claims submitted by healthcare providers and third-party payers in connection therewith.
  - 308. Compliance with applicable Medicare, Medicaid and the various other federal and

state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Massachusetts in connection with Defendant's conduct. Compliance with applicable Massachusetts statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the Commonwealth of Massachusetts.

- 309. Had the Commonwealth of Massachusetts known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 310. As a result of Defendant's violations of Mass. Gen. Laws Ann. Chap. 12 § 5B, the Commonwealth of Massachusetts has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 311. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to Mass. Gen. Laws Ann. Chap. 12 § 5(c)(2), on behalf of themselves and the Commonwealth of Massachusetts.
- 312. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the Commonwealth of Massachusetts, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

#### To the COMMONWEALTH OF MASSACHUSETTS:

- (1) Three times the amount of actual damages which the Commonwealth of Massachusetts has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the Commonwealth of Massachusetts;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

## To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to Mass. Gen. Laws Ann. Chap. 12, §5F and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

# COUNT XIV - MICHIGAN MEDICAID FALSE CLAIMS ACT

- 313. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 314. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Michigan to recover treble damages and civil penalties under Michigan's Medicaid False Claims Act, Mich. Comp. Laws Ann. § 400.603 *et seq.*, which provides in pertinent part as follows:
  - Sec. 3. (1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for medicaid benefits; and
  - (2) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a medicaid benefit....
  - 315. In addition, Mich. Comp. Laws Ann. § 400.604 prohibits the solicitation or

receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Michigan Medicaid program.

- 316. Defendant violated the Michigan Medicaid False Claims Act by engaging in the conduct alleged herein.
- 317. Defendant further violated Michigan law and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Michigan by its deliberate and systematic violation of federal and state laws, including the FDCA and federal AKA, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 318. The State of Michigan, by and through the Michigan Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
- 319. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Michigan in connection with Defendant's conduct. Compliance with applicable Michigan statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Michigan.
- 320. Had the State of Michigan known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

- 321. As a result of Defendant's violations of the Michigan Medicaid False Claims Act, the State of Michigan has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 322. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the Michigan Medicaid False Claims Act on behalf of themselves and the State of Michigan.
- 323. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Michigan, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

## To the STATE OF MICHIGAN:

- (1) Three times the amount of actual damages which the State of Michigan has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the State of Michigan;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

## To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to the Medicaid False Claims Act and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT XV - MINNESOTA FALSE CLAIMS ACT

- 324. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 325. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Minnesota to recover treble damages and civil penalties under the Minnesota False Claims Act, M.S.A. § 15C.01, *et seq*.
- 326. Minnesota False Claims Act, M.S.A. § 15C.02, provides for liability for any person who:
  - (1) knowingly presents, or causes to be presented, to an officer or employee of the state or a political subdivision a false or fraudulent claim for payment or approval;
  - (2) knowingly makes or uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a political subdivision; knowingly conspires to either present a false or fraudulent claim to the state or a political subdivision for payment or approval or makes, uses, or causes to be made or used a false record or statement to obtain payment or approval of a false or fraudulent claim;
  - (3) has possession, custody, or control of public property or money used, or to be used, by the state or a political subdivision and knowingly delivers or causes to be delivered to the state or a political subdivision less money or property than the amount for which the person receives a receipt;
  - (4) is authorized to prepare or deliver a receipt for money or property used, or to be used, by the state or a political subdivision and knowingly prepares or delivers a receipt that falsely represents the money or property;
  - (5) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state or a political subdivision who lawfully may not sell or pledge the property; and/or
  - (6) knowingly makes or uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or a political subdivision.
  - 327. In addition, M.S.A. § 256B.0914, prohibits the solicitation or receipt of any

remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Minnesota Medicaid program.

- 328. Defendant violated the Minnesota False Claims Act by engaging in the conduct alleged herein.
- 329. Defendant further violated the Minnesota False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Minnesota by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA and M.S.A. § 256B.0914, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 330. The State of Minnesota, by and through the Minnesota Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
- 331. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Minnesota in connection with Defendant's conduct. Compliance with applicable Minnesota statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Minnesota.
- 332. Had the State of Minnesota known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were

premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

- 333. As a result of Defendant's violations of the Minnesota False Claims Act, the State of Minnesota has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 334. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the Minnesota False Claims Act, on behalf of themselves and the State of Minnesota.
- 335. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Minnesota, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

## To the STATE OF MINNESOTA:

- (1) Three times the amount of actual damages which the State of Minnesota has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$11,000 for each false claim which Defendant caused to be presented to the State of Minnesota;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

## To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to the Minnesota False Claims Act and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;

- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT XVI – MONTANA FALSE CLAIMS ACT

- 336. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 337. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Montana to recover treble damages and civil penalties under the Montana False Claims Act, MCA § 17-8-401, *et seq*.
- 338. Montana's False Claims Act, MCA § 17-8-403, provides for liability for any person who:
  - (a) knowingly presents or causes to be presented to an officer or employee of the governmental entity a false or fraudulent claim for payment or approval;
  - (b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the governmental entity;
  - (c) conspires to defraud the governmental entity by getting a false or fraudulent claim allowed or paid by the governmental entity;
  - (d) has possession, custody, or control of public property or money used or to be used by the governmental entity and, with the intent to defraud the governmental entity or to willfully conceal the property, delivers or causes to be delivered less property or money than the amount for which the person receives a certificate or receipt;
  - (e) is authorized to make or deliver a document certifying receipt of property used or to be used by the governmental entity and, with the intent to defraud the governmental entity or to willfully conceal the property, makes or delivers a receipt without knowing that the information on the receipt is true;
  - (f) knowingly buys or receives as a pledge of an obligation or debt public property of the governmental entity from any person who

may not lawfully sell or pledge the property;

- (g) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the governmental entity or its contractors; or
- (h) as a beneficiary of an inadvertent submission of a false or fraudulent claim to the governmental entity, subsequently discovers the falsity of the claim or that the claim is fraudulent and fails to disclose the false or fraudulent claim to the governmental entity within a reasonable time after discovery of the false or fraudulent claim.
- 339. In addition, MCA § 45-6-313 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Montana Medicaid program.
- 340. Defendant violated the Montana False Claims Act by engaging in the conduct alleged herein.
- 341. Defendant furthermore violated the Montana False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Montana by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA and MCA § 45-6-313, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 342. The State of Montana, by and through the Montana Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
  - 343. Compliance with applicable Medicare, Medicaid and the various other federal and

state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Montana in connection with Defendant's conduct. Compliance with applicable Montana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Montana.

- 344. Had the State of Montana known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 345. As a result of Defendant's violations of the Montana False Claims Act, the State of Montana has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 346. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the Montana False Claims Act, on behalf of themselves and the State of Montana.
- 347. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Montana, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

## To the STATE OF MONTANA:

- (1) Three times the amount of actual damages which the State of Montana has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each

- false claim which Defendant caused to be presented to the State of Montana:
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

#### To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to Montana False Claims Act and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

# COUNT XVII - NEVADA FALSE CLAIMS ACT

- 348. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 349. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, N.R.S. § 357.010, *et seq*.
  - 350. N.R.S. § 357.040(1) provides liability for any person who:
    - (a) knowingly presents or causes to be presented a false claim for payment or approval;
    - (b) knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim;
    - (c) conspires to defraud by obtaining allowance or payment of a false claim; and/or

\* \* \*

(h) is a beneficiary of an inadvertent submission of a false claim and, after

discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time.

- 351. In addition, N.R.S. § 422.560 prohibits the solicitation, acceptance or receipt of anything of value in connection with the provision of medical goods or services for which payment may be made, in whole or in part, under the Nevada Medicaid program.
  - 352. Defendant violated N.R.S. § 422.560 by engaging in the conduct alleged herein.
- 353. Defendant further violated N.R.S. § 357.040(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Nevada by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA and N.R.S. § 422.560, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 354. The State of Nevada, by and through the Nevada Medicaid program and other state healthcare programs, and unaware of Defendant' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
- 355. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Nevada in connection with Defendant's conduct. Compliance with applicable Nevada statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Nevada.
- 356. Had the State of Nevada known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

- 357. As a result of Defendant's violations of N.R.S. § 357.040(1), the State of Nevada has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 358. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.R.S. § 357.080(1), on behalf of themselves and the State of Nevada.
- 359. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request that this Court award the following damages to the following parties and against Defendant:

## To the STATE OF NEVADA:

- (1) Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$2,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the State of Nevada:
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

## To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to N.R.S. § 357.210 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action:
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

# COUNT XVIII – NEW JERSEY FALSE CLAIMS ACT

- 360. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 361. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of New Jersey to recover treble damages and civil penalties under the New Jersey False Claims Act, N.J.S.A. § 2A:32C-1, *et seq*.
- 362. The New Jersey False Claims Act, N.J.S.A. § 2A:32C-3, provides for liability for any person who:
  - a. Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
  - b. Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;
  - c. Conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State;
  - d. Has possession, custody, or control of public property or money used or to be used by the State and knowingly delivers or causes to be delivered less property than the amount for which the person receives a certificate or receipt;
  - e. Is authorized to make or deliver a document certifying receipt of property used or to be used by the State and, intending to defraud the entity, makes or delivers a receipt without completely knowing that the information on the receipt is true;
  - f. Knowingly buys, or receives as a pledge of an obligation or debt, public property from any person who lawfully may not sell or pledge the property; or
  - g. Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

- 363. In addition, N.J.S.A. § 30:4D-17 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made in whole or in part under the New Jersey Medicaid program.
- 364. Defendant violated the New Jersey False Claims Act by engaging in the conduct alleged herein.
- 365. Defendant further violated the New Jersey False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New Jersey by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA and N.J.S.A. § 30:4D-17, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 366. The State of New Jersey, by and through the New Jersey Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
- 367. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of New Jersey in connection with Defendant's conduct. Compliance with applicable New Jersey statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New Jersey.
- 368. Had the State of New Jersey known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct

failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

- 369. As a result of Defendant's violations of the New Jersey False Claims Act, the State of New Jersey has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 370. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the New Jersey False Claims Act, on behalf of themselves and the State of New Jersey.
- 371. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of New Jersey, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

## To the STATE OF NEW JERSEY:

- (1) Three times the amount of actual damages which the State of New Jersey has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$11,000 for each false claim which Defendant caused to be presented to the State of New Jersey;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

## To Plaintiffs-Relators:

(1) The maximum amount allowed pursuant to New Jersey False Claims Act and/or any other applicable provision of law;

- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

# COUNT XIX - NEW MEXICO MEDICAID FALSE CLAIMS ACT

- 372. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 373. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 27-14-1, *et seq.*, which provides, in pertinent part, as follows:

## A person shall not:

- (1) knowingly present, or cause to be presented, to an employee, officer or agent of the state or to a contractor, grantee, or other recipient of state funds, a false or fraudulent claim for payment or approval;
- (2) knowingly make or use, or cause to be made or used, a false, misleading or fraudulent record or statement to obtain or support the approval of or the payment on a false or fraudulent claim; or
- (3) conspire to defraud the state by obtaining approval or payment on a false or fraudulent claim ....
- 374. In addition, N.M. Stat. Ann. §§ 30-44-7, *et seq.*, prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the New Mexico Medicaid program.
- 375. Defendant violated N.M. Stat. Ann. § 30-44-7, *et seq.*, by engaging in the conduct alleged herein.
  - 376. Defendant further violated N.M. Stat. Ann. §§ 27-14-1, et seq., and knowingly

caused hundreds of thousands of false claims to be made, used and presented to the State of New Mexico by its deliberate and systematic violation of federal and state laws, including the FDCA and federal AKA, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.

- 377. The State of New Mexico, by and through the New Mexico Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
- 378. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of New Mexico in connection with Defendant's conduct. Compliance with applicable New Mexico statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of New Mexico.
- 379. Had the State of New Mexico known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 380. As a result of Defendant's violations of N.M. Stat. Ann. §§ 27-14-1, et seq., the State of New Mexico has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 381. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.M. Stat. Ann. §§

27-14-1, et seq., on behalf of themselves and the State of New Mexico.

382. This Court is requested to accept supplemental jurisdiction of this related state claim, as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of New Mexico, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

## To the STATE OF NEW MEXICO:

- (1) Three times the amount of actual damages which the State of New Mexico has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the State of New Mexico;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

## To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to N.M. Stat. Ann. §§ 27-14-1, *et seq.*, and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT XX – NEW YORK FALSE CLAIMS ACT

- 383. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 384. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of New York to recover treble damages and civil penalties under the New York State False Claims

Act, State Finance Law § 189, which imposes liability on any person who:

- (a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or local government, a false or fraudulent claim for payment or approval;
- (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or local government; or
- (c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.
- 385. In addition, New York law prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the New York Medicaid program.
  - 386. Defendant violated New York law by engaging in the conduct alleged herein.
- 387. Defendant further violated the New York State False Claims Act, and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New York, by its deliberate and systematic violation of federal and state laws, including the FDCA and federal AKA, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 388. The State of New York, by and through the New York Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
- 389. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of New York in connection with Defendant's conduct. Compliance with applicable New York statutes, regulations and Pharmacy

Manuals was also an express condition of payment of claims submitted to the State of New York

- 390. Had the State of New York known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 391. As a result of Defendant's violations of the New York State False Claims Act, the State of New York has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 392. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the New York State False Claims Act, on behalf of themselves and the State of New York.
- 393. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of New York, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

## To the STATE OF NEW YORK:

- (1) Three times the amount of actual damages which the State of New York has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the State of New York;
- (3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

## To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to the New York State False Claims Act, and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

# COUNT XXI - NORTH CAROLINA FALSE CLAIMS ACT

- 394. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 395. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, N.C.G.S.A. § 1-605, *et seq*.
- 396. North Carolina's False Claims Act, N.C.G.S.A. § 1-607, provides for liability for any person who:
  - (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;
  - (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
  - (3) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7) of this section;
  - (4) Has possession, custody, or control of property or money used or to be used by the State and knowingly delivers or causes to be delivered less than all of that money or property;
  - (5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the State and, intending to defraud

- the State, makes or delivers the receipt without completely knowing that the information on the receipt is true;
- (6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any officer or employee of the State who lawfully may not sell or pledge the property; or
- (7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State.
- 397. In addition, N.C.G.S.A. § 108A-63 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the North Carolina Medicaid program.
- 398. Defendant violated the North Carolina False Claims Act by engaging in the conduct alleged herein.
- 399. Defendant further violated the North Carolina False Claims Act, and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of North Carolina, by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA and N.C.G.S.A. § 108A-63, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 400. The State of North Carolina, by and through the North Carolina Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
- 401. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express

condition of payment of claims submitted to the State of North Carolina in connection with Defendant's conduct. Compliance with applicable North Carolina statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of North Carolina.

- 402. Had the State of North Carolina known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 403. As a result of Defendant's violations of the North Carolina False Claims Act, the State of North Carolina has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 404. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the North Carolina False Claims Act, on behalf of themselves and the State of North Carolina.
- 405. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of North Carolina, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

## To the STATE OF NORTH CAROLINA:

- (1) Three times the amount of actual damages which the State of North Carolina has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each

- false claim which Defendant caused to be presented to the State of North Carolina;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

#### To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to North Carolina False Claims Act and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

# COUNT XXII - OKLAHOMA MEDICAID FALSE CLAIMS ACT

- 406. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 407. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, 63 Okl. St. Ann. § 5053, *et seq*.
- 408. Oklahoma's Medicaid False Claims Act, 63 Okl. St. Ann. § 5053.1, provides for liability for any person who:
  - 1. Knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;
  - 2. Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
  - 3. Conspires to defraud the State by getting a false or fraudulent claim allowed or paid;
  - 4. Has possession, custody, or control of property or money used, or to be

- used, by the state and, intending to defraud the State or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt;
- 5. Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the State and, intending to defraud the State, makes or delivers the receipt without completely knowing that the information on the receipt is true;
- 6. Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state, who lawfully may not sell or pledge the property; or
- 7. Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.
- 409. In addition, 56 Okl. St. Ann. § 1005 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made in whole or in part, under the Oklahoma Medicaid program.
- 410. Defendant violated the Oklahoma Medicaid False Claims Act by engaging in the conduct alleged herein.
- 411. Defendant furthermore violated the Oklahoma Medicaid False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Oklahoma by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA and 56 Okl. St. Ann. § 1005, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 412. The State of Oklahoma, by and through the Oklahoma Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

- 413. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Oklahoma in connection with Defendant's conduct. Compliance with applicable Oklahoma statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Oklahoma.
- 414. Had the State of Oklahoma known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 415. As a result of Defendant's violations of the Oklahoma Medicaid False Claims

  Act, the State of Oklahoma has been damaged in an amount far in excess of millions of dollars,

  exclusive of interest.
- 416. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the Oklahoma Medicaid False Claims Act, on behalf of themselves and the State of Oklahoma.
- 417. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Oklahoma, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

# To the STATE OF OKLAHOMA:

(1) Three times the amount of actual damages which the State of Oklahoma has sustained as a result of Defendant's conduct;

- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the State of Oklahoma;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

#### To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to Oklahoma Medicaid False Claims Act and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT XXIII - RHODE ISLAND FALSE CLAIMS ACT

- 418. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 419. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island False Claims Act, Gen. Laws 1956, § 9-1.1-1, *et seq*.
- 420. Rhode Island's False Claims Act, Gen. Laws 1956, § 9-1.1-3, provides for liability for any person who:
  - (1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
  - (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
  - (3) conspires to defraud the state by getting a false or fraudulent claim

allowed or paid;

- (4) has possession, custody, or control of property or money used, or to be used, by the state and, intending to defraud the state or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt;
- (5) authorized to make or deliver a document certifying receipt of property used, or to be used, by the state and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;
- (6) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state, or a member of the guard, who lawfully may not sell or pledge the property; or
- (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state.
- 421. In addition, Gen. Laws 1956, § 40-8.2-9 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Rhode Island Medicaid program.
- 422. Defendant violated the Rhode Island False Claims Act by engaging in the conduct alleged herein.
- 423. Defendant further violated the Rhode Island False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Rhode Island by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA and Gen. Laws 1956, § 40-8.2-9, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
  - 424. The State of Rhode Island, by and through the Rhode Island Medicaid program

and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

- 425. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Rhode Island in connection with Defendant's conduct. Compliance with applicable Rhode Island statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Rhode Island.
- 426. Had the State of Rhode Island known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 427. As a result of Defendant's violations of the Rhode Island False Claims Act, the State of Rhode Island has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 428. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the Rhode Island False Claims Act, on behalf of themselves and the State of Rhode Island.
- 429. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Rhode Island, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

## To the STATE OF RHODE ISLAND:

- (1) Three times the amount of actual damages which the State of Rhode Island has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the State of Rhode Island;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

## To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to Rhode Island False Claims Act and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT XXIV – TENNESSEE FALSE CLAIMS ACT

- 430. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 431. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, *et seq*.
  - 432. Section 71-5-182(a)(1) provides liability for any person who:
    - (A) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;

- (B) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false; or
- (C) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.
- 433. Defendant violated Tenn. Code Ann. § 71-5-1 82(a)(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Tennessee by its deliberate and systematic violation of federal and state laws, including the FDCA and AKA, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 434. The State of Tennessee, by and through the Tennessee Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
- 435. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with Defendant's conduct. Compliance with applicable Tennessee statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Tennessee.
- 436. Had the State of Tennessee known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
  - 437. As a result of Defendant's violations of Tenn. Code Ann. § 71-5-182(a)(1), the

State of Tennessee has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

- 438. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1), on behalf of themselves and the State of Tennessee.
- 439. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damaged to the State of Tennessee, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

### To the STATE OF TENNESSEE:

- (1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the State of Tennessee;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

## To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to Tenn. Code Ann. § 71-5-183(c) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

# COUNT XXV – TEXAS FALSE CLAIMS ACT

- 440. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 441. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Texas to recover double damages and civil penalties under V.T.C.A. Hum. Res. Code § 36.001, *et seq.* 
  - 442. V.T.C.A. Hum. Res. Code § 36.002 provides liability for any person who:
    - (1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:
      - (a) on an application for a contract, benefit, or payment under the Medicaid program; or
      - (b) that is intended to be used to determine its eligibility for a benefit or payment under the Medicaid program;
    - (2) knowingly or intentionally concealing or failing to disclose an event:
      - (a) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of:
        - (i) the person, or
        - (ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and
      - (b) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;

\* \* \*

(4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:

\* \* \*

- (b) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;
- (5) knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift,

- money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program.
- 443. Defendant violated V.T.C.A. Hum. Res. Code § 36.002 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Texas by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA and § 36.002, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 444. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
- 445. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with Defendant's conduct. Compliance with applicable Texas statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Texas.
- 446. Had the State of Texas known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 447. As a result of Defendant's violations of V.T.C.A. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

- 448. Defendant did not, within 30 days after it first obtained information as to such violations, furnish such information to officials of the State of Texas responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and has not otherwise furnished information to the State of Texas regarding the claims for reimbursement at issue.
- 449. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to V.T.C.A. Hum. Res. Code § 36.101, on behalf of themselves and the State of Texas.
- 450. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Texas, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

### To the STATE OF TEXAS:

- (1) Two times the amount of actual damages which the State of Texas has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$10,000 pursuant to V.T.C.A. Hum. Res. Code § 36.025(a)(3) for each false claim which Defendant cause to be presented to the State of Texas;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

### To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to V.T.C.A. Hum. Res. Code § 36.110, and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;

- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT XXVI – VIRGINIA FRAUD AGAINST TAXPAYERS ACT

- 451. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 452. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the Commonwealth of Virginia for treble damages and penalties under Virginia Fraud Against Tax Payers Act, §8.01-216.3a, which provides liability for any person who:
  - (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
  - (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth;
  - (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim; or

\* \* \*

- (9) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.
- 453. In addition, VA Code Ann. § 32.1-315 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any good, service or item for which payment may be made, in whole or in part, under the Virginia Medicaid program.

- 454. Defendant violated VA Code Ann. § 32.1-315 by engaging in the conduct alleged herein.
- 455. Defendant furthermore violated Virginia's Fraud Against Tax Payers Act, § 8.01-216.3a, and knowingly caused hundreds of thousands of false claims to be made, used and presented to the Commonwealth of Virginia by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA, VA Code Ann. § 32.1-315 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 456. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
- 457. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Virginia in connection with Defendant's conduct. Compliance with applicable Virginia statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the Commonwealth of Virginia.
- 458. Had the Commonwealth of Virginia known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
  - 459. As a result of Defendant's violations of Virginia's Fraud Against Tax Payers Act,

§8.01-216.3a, the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

- 460. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Virginia's Fraud Against Tax Payers Act, §8.01-216.3, on behalf of themselves and the Commonwealth of Virginia.
- 461. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the Commonwealth of Virginia, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

### To the COMMONWEALTH OF VIRGINIA:

- (1) Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the Commonwealth of Virginia;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

## To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to VA Code Ann. § 32.1-315 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT XXVII - WASHINGTON MEDICAID FRAUD ACT

- 462. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 463. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Washington to recover treble damages and civil penalties under the Washington Medicaid Fraud Act, RCWA 74.66.005, *et seq*.
  - 464. RCWA 74.66.020, in pertinent part, provides for liability for any person who:
    - (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
    - (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
    - (c) Conspires to commit one or more of the violations in this subsection (1).
- 465. In addition, RCWA 74.09.240 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Washington Medicaid program.
- 466. Defendant violated RCWA 74.09.240 by engaging in the conduct described herein.
- 467. Defendant furthermore violated the Washington Medicaid Fraud Act, RCWA 74.66.005, *et seq.*, and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Washington, by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA, and RCWA 74.09.240, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement

by the Government Healthcare Programs.

- 468. The State of Washington, by and through the Washington Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
- 469. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Washington in connection with Defendant's conduct. Compliance with applicable Washington statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Washington.
- 470. Had the State of Washington known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 471. As a result of Defendant's violations of the Washington Medicaid Fraud Act, RCWA 74.66.005, *et seq.*, the State of Washington has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 472. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the Washington Medicaid Fraud Act, RCWA 74.66.005, *et seq.*, on behalf of themselves and the State of Washington.
- 473. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages

to the State of Washington, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

### To the STATE OF WASHINGTON:

- (1) Three times the amount of actual damages which the State of Washington has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which Defendant caused to be presented to the State of Washington;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

#### To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to the Washington Medicaid Fraud Act, RCWA 74.66.005, *et seq.*, and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

### COUNT XXVIII - WISCONSIN MEDICAID FALSE CLAIMS ACT

- 474. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 475. This is a *qui tam* action brought by Plaintiffs-Relators on behalf of the State of Wisconsin to recover treble damages and civil penalties under the Wisconsin False Claims Act, W.S.A. § 20.931, *et seq*.
  - 476. The Wisconsin False Claims Act, W.S.A. § 20.931, et seq., provides for liability

for any person who:

- (a) Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance;
- (b) Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance;
- (c) Conspires to defraud this state by obtaining allowance or payment of a false claim for medical assistance, or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program;

\* \* \*

- (g) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease any obligation to pay or transmit money or property to the Medical Assistance program; and/or
- (h) Is a beneficiary of the submission of a false claim for medical assistance to any officer, employee, or agent of this state, knows that the claim is false, and fails to disclose the false claim to this state within a reasonable time after the person becomes aware that the claim is false.
- 477. In addition, W.S.A. § 49.49 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Wisconsin Medicaid program.
- 478. Defendant violated the Wisconsin False Claims Act by engaging in the conduct alleged herein.
- 479. Defendant further violated the Wisconsin False Claims Act and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Wisconsin by its deliberate and systematic violation of federal and state laws, including the FDCA, federal

AKA and W.S.A. § 49.49, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.

- 480. The State of Wisconsin, by and through the Wisconsin Medicaid program and other state healthcare programs, and unaware of Defendant's conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
- 481. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Wisconsin in connection with Defendant's conduct. Compliance with applicable Wisconsin statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Wisconsin.
- 482. Had the State of Wisconsin known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 483. As a result of Defendant's violations of the Wisconsin False Claims Act, the State of Wisconsin has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 484. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the Wisconsin False Claims Act, on behalf of themselves and the State of Wisconsin.

485. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Wisconsin, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

### To the STATE OF WISCONSIN:

- (1) Three times the amount of actual damages which the State of Wisconsin has sustained as a result of Defendant's conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the State of Wisconsin;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

## To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to Wisconsin False Claims Act and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT XXIX – D.C. PROCUREMENT REFORM AMENDMENT ACT

- 486. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 487. This is a *qui tam* action brought by Plaintiffs-Relators and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13, *et seq*.

- 488. D.C. Code § 2-308.14(a) provides liability for any person who:
  - (1) knowingly presents, or causes to be presented, to an officer or employee of the District, a false claim for payment or approval;
  - (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;
  - (3) conspires to defraud the District by getting a false claim allowed or paid by the District; or

\* \* \*

- (8) is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District.
- 489. In addition, D.C. Code § 4-802(c) prohibits soliciting, accepting, or agreeing to accept any type of remuneration for the following:
  - (1) Referring a recipient to a particular provider of any item or service or for which payment may be made under the District of Columbia Medicaid program; or
  - (2) Recommending the purchase, lease, or order of any good, facility, service, or item for which payment may be made under the District of Columbia Medicaid Program.
- 490. Defendant violated D.C. Code § 4-802(c) by engaging in the illegal conduct alleged herein.
- 491. Defendant further violated D.C. Code § 2-308.14(a) and knowingly caused thousands of false claims to be made, used and presented to the District of Columbia by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA D.C. Code § 4-802(c), and by virtue of the fact that none of the claims submitted in connection with its illegal conduct were even eligible for reimbursement by the Government Healthcare Programs.

- 492. The District of Columbia, by and through the District of Columbia Medicaid program and other District of Columbia healthcare programs, and unaware of Defendant's illegal conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
- 493. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the District of Columbia in connection with Defendant's illegal conduct. Compliance with applicable District of Columbia statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the District of Columbia.
- 494. Had the District of Columbia known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 495. As a result of Defendant's violations of D.C. Code § 2-308.14(a), the District of Columbia has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 496. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of themselves and the District of Columbia.
- 497. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts

separate damage to the District of Columbia, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

### To the DISTRICT OF COLUMBIA:

- (1) Three times the amount of actual damages which the District of Columbia has sustained as a result of Defendant's illegal conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the District of Columbia;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

### To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to D.C. Code § 2-308.15(f) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT XXX - CITY OF CHICAGO FALSE CLAIMS ACT

- 498. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 499. This is a *qui tam* action brought by Plaintiffs-Relators and the City of Chicago to recover treble damages and civil penalties under the Chicago False Claims Act, Chapter 1-22-10, *et seq.* 
  - 500. The Chicago False Claims Act, Chapter 1-22-20, provides for liability for any

## person who:

- (1) knowingly presents, or causes to be presented, to an official or employee of the city a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the city;
- (3) conspires to defraud the city by getting a false or fraudulent claim allowed or paid;
- (4) has possession, custody, or control of property or money used, or to be used, by the city and, intending to defraud the city or to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt;
- (5) authorized to make or deliver a document certifying receipt of property used, or to be used, by the city and, intending to defraud the city, makes or delivers the receipt without complete knowledge that the information on the receipt is true;
- (6) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the city who lawfully may not sell or pledge the property; or
- (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the city.
- 501. Defendant violated Chicago False Claims Act, and further knowingly caused thousands of false claims to be made, used and presented to the City of Chicago by its deliberate and systematic violation of federal and state laws, including the FDCA and federal AKA, and by virtue of the fact that none of the claims submitted in connection with its illegal conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 502. The City of Chicago, by and through the City of Chicago Medicaid program and other state healthcare programs, and unaware of Defendant's illegal conduct, paid the claims

submitted by healthcare providers and third-party payers in connection therewith.

- 503. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the City of Chicago in connection with Defendant's illegal conduct. Compliance with applicable the City of Chicago statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the City of Chicago.
- 504. Had the City of Chicago known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 505. As a result of Defendant's violations of the City of Chicago False Claims Act, the City of Chicago has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 506. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Chicago False Claims Act on behalf of themselves and the City of Chicago.
- 507. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the City of Chicago, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

### To the CITY OF CHICAGO:

- (1) Three times the amount of actual damages which the City of Chicago has sustained as a result of Defendant's illegal conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the City of Chicago;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

#### To Plaintiffs-Relators:

- (1) The maximum amount allowed pursuant to the Chicago False Claims Act and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiffs-Relators incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

## COUNT XXXI - CITY OF NEW YORK FALSE CLAIMS ACT

- 508. Plaintiffs-Relators reallege and incorporate by reference the prior paragraphs as though fully set forth herein.
- 509. This is a *qui tam* action brought by Plaintiffs-Relators and the City of New York to recover treble damages and civil penalties under the New York City False Claims Act, Admin. Code §7-801, *et seq*.
- 510. The New York City False Claims Act, Admin. Code §7-803, provides liability for any person who:
  - 1. knowingly presents, or causes to be presented, to any city officer or employee, a false claim for payment or approval by the city;

- 2. knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the city;
- 3. conspires to defraud the city by getting a false claim allowed or paid by the city;
- 4. has possession, custody, or control of property or money used, or to be used, directly or indirectly, by the city and, intending to defraud the city or willfully conceal the property or money, delivers, or causes to be delivered, less property or money than the amount for which the person receives a certificate or receipt;
- 5. is authorized to make or deliver a document certifying receipt of property used, or to be used, directly or indirectly, by the city and, intending to defraud the city, makes or delivers the receipt without completely knowing that the information on the receipt is true;
- 6. knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the city knowing that such officer or employee lawfully may not sell or pledge the property; or
- 7. knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease, directly or indirectly, an obligation to pay or transmit money or property to the city.
- 511. Defendant furthermore violated the New York City False Claims Act, Admin. Code §7-803, and knowingly caused thousands of false claims to be made, used and presented to the City of New York by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKA, and by virtue of the fact that none of the claims submitted in connection with its illegal conduct were even eligible for reimbursement by the Government Healthcare Programs.
- 512. The City of New York, by and through the City of New York Medicaid program and other state healthcare programs, and unaware of Defendant's illegal conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.
  - 513. Compliance with applicable Medicare, Medicaid and the various other federal and

state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the City of New York in connection with Defendant's illegal conduct. Compliance with applicable City of New York statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the City of New York.

- 514. Had the City of New York known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the Government Healthcare Programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.
- 515. As a result of Defendant's violations of New York City False Claims Act, Admin. Code §7-803, the City of New York has been damaged in an amount far in excess of millions of dollars, exclusive of interest.
- 516. Plaintiffs-Relators are private citizens with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to the New York City False Claims Act, on behalf of themselves and the City of New York.
- 517. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the City of New York, in the operation of its Medicaid program.

WHEREFORE, Plaintiffs-Relators respectfully request this Court to award the following damages to the following parties and against Defendant:

### To the CITY OF NEW YORK:

(1) Three times the amount of actual damages which the City of New York has sustained as a result of Defendant's illegal conduct;

- (2) A civil penalty of not less than \$5,000 and not more than \$10,000 for each false claim which Defendant caused to be presented to the City of New York;
- Prejudgment interest; and (3)
- **(4)** All costs incurred in bringing this action. To Plaintiffs-Relators:
- (1) The maximum amount allowed pursuant to the New York City False Claims Act and/or any other applicable provision of law;
- Reimbursement for reasonable expenses which Plaintiffs-Relators incurred (2) in connection with this action;
- An award of reasonable attorneys' fees and costs; and (3)
- Such further relief as this Court deems equitable and just. **(4)**

# **JURY DEMAND**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs-Relators demand a trial by jury on all Counts.

Dated: March 23, 2016 Respectfully submitted,

> SHEPHERD, FINKELMAN, MILLER & SHAH, LLP

/s/ Laurie Rubinow James E. Miller Laurie Rubinow (LR6637) 65 Main Street Chester, CT 06412

Tel: (860) 526-1100 Fax: (866) 300-7367

Rose F. Luzon Valerie L. Chang Chiharu G. Sekino Shepherd, Finkelman, Miller & Shah, LLP 401 West 'A' Street, Suite 2550 San Diego, CA 92101

Tel: (619) 235-2416

Fax: (866) 300-7367

McEldrew Young
Eric L. Young
James J. McEldrew, III
Brandon J. Lauria
526 E. Township Line Road, Suite 100
Blue Bell, PA 19422
Tel: (215) 367-5151
Fax: (215) 367-5143

David J. Caputo David C. Williams Kline & Specter, P.C. 1525 Locust Street Philadelphia, PA 19102 Tel: (215) 772-1000 Fax: (215) 772-1359

David A. Bocian Kessler Topaz Meltzer & Check, LLP 280 King of Prussia Road Radnor, PA 19087

Tel: (610) 667-7706 Fax: 610-667-7056

Attorneys for Plaintiffs-Relators